IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	**MDL 2804**
THIS DOCUMENT RELATES TO:	)	**Judge Dan Aaron Polster**
BOARD OF EDUCATION OF THORNTON TOWNSHIP HIGH SCHOOLS, DISTRICT 205,[1] ROCHESTER PUBLIC SCHOOL DISTRICT, MINNETONKA PUBLIC SCHOOL DISTRICT, MASON COUNTY PUBLIC SCHOOLS, BALTIMORE CITY PUBLIC SCHOOLS, EAST AURORA PUBLIC SCHOOLS, DISTRICT 131, THORNTON FRACTIONAL HIGH SCHOOLS, DISTRICT 215, JOLIET PUBLIC SCHOOLS, DISTRICT 86, FAYETTE COUNTY PUBLIC SCHOOLS, LARUE COUNTY PUBLIC SCHOOLS, BULLITT COUNTY PUBLIC SCHOOLS, BREATHITT COUNTY PUBLIC SCHOOLS, ESTILL COUNTY PUBLIC SCHOOLS, HARRISON COUNTY PUBLIC SCHOOLS, HART COUNTY PUBLIC SCHOOLS, JEFFERSON COUNTY PUBLIC SCHOOLS, JOHNSON COUNTY PUBLIC SCHOOLS, LAWRENCE COUNTY PUBLIC SCHOOLS, MARTIN COUNTY PUBLIC SCHOOLS, MENIFEE COUNTY PUBLIC SCHOOLS, OWSLEY COUNTY PUBLIC SCHOOLS, WOLFE COUNTY PUBLIC SCHOOLS, BANGOR SCHOOL DEPARTMENT, CAPE ELIZABETH SCHOOL DISTRICT, MAINE REGIONAL SCHOOL UNIT ("RSU") 10, MAINE RSU 13, MAINE RSU 25, MAINE RSU 26, MAINE RSU 29, MAINE RSU 34, MAINE RSU 40, MAINE RSU 50, MAINE RSU 57, MAINE RSU 60, MAINE RSU 71, MAINE RSU 9, MAINE SCHOOL ADMINISTRATIVE DISTRICT ("SAD") 11,	)	**CLASS ACTION COMPLAINT**

[1] For the purpose of brevity, each Plaintiff hereafter will omit the Board title from their name.

MAINE SAD 15, MAINE SAD 28/FIVE TOWN CENTRAL SCHOOL DISTRICT, MAINE SAD 35, MAINE SAD 44, MAINE SAD 53, MAINE SAD 55, MAINE SAD 6, MAINE SAD 61, MAINE SAD 72, PORTLAND SCHOOL DISTRICT, SCARBOROUGH SCHOOL DISTRICT, SOUTH PORTLAND SCHOOL DISTRICT, ST. GEORGE MUNICIPAL SCHOOL DISTRICT, WATERVILLE SCHOOL DISTRICT, ELLSWORTH SCHOOL DEPARTMENT; GOSHEN SCHOOL DISTRICT, KEARSARGE RSU-SCHOOL ADMINISTRATIVE UNIT 65, LEBANON SCHOOL DISTRICT, PITTSFIELD SCHOOL DISTRICT, TAMWORTH SCHOOL DISTRICT, on behalf of themselves and others similarly situated,

v.

CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., ENDO INTERNATIONAL PLC, ENDO HEALTH SOLUTIONS INC., ENDO PHARMACEUTICALS INC., JANSSEN PHARMACEUTICALS, INC., ORTH-MCNEIL-JANSSEN PHARMACEUTICALS, INC., n/k/a/ JANSSEN PHARMACEUTICA, INC., n/k/a JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, INC, ALLERGAN PLC f/k/a ACTAVIS PLC, WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a/ WATSON PHARMA, INC., AMERISOURCEBERGEN CORPORATION, CARDINAL HEALTH, INC., McKESSON CORPORATION, CVS HEALTH CORPORATION, CVS INDIANA L.L.C., CVS RX SERVICES, INC., CVS TN DISTRIBUTION, LLC, CVS PHARMACY, INC., OMNICARE DISTRIBUTION CENTER LLC, WALGREENS BOOTS ALLIANCE,

INC., a/k/a WALGREEN CO., WALGREEN EASTERN CO., INC., and WALMART INC., f/k/a WAL-MART STORES, INC., WAL-MART STORES EAST, LP, WSE MANAGEMENT, LLC, WSE INVESTMENT, LLC, WAL-MART STORES EAST, INC., RITE AID CORPORATION, RITE AID HDQTRS. CORP., RITE AID OF MARYLAND, INC., d/b/a RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC., ECKERD CORPORATION d/b/a RITE AID LIVERPOOL DISTRIBUTION CENTER,

Defendants.

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CLASS ACTION COMPLAINT AND JURY DEMAND

In accordance with 28 U.S.C. §1407 and Case Management Order One, *In Re: National Prescription Opiate Litig.*, No. 17-MD-2804, ¶ 6.a., Dkt. 232 (N.D. Oh. Apr. 11, 2018) (Polster, J.), this civil action is filed directly in this District for purposes of coordinated and consolidated pretrial proceedings.

I. INTRODUCTION.

1. American public schools perform a function which lies at the very heart of our democracy, providing an education to every student who walks in their doors. For the last two decades, in addition to providing this essential and challenging governmental function, public schools have been shouldering perhaps the most profound and enduring consequences of the nationwide opioid epidemic. Children who are exposed to opioids *in utero* frequently develop cognitive and behavioral disabilities as a result, and they require extra interventions and supports throughout their education. Public schools are, in turn, required to provide special education and related services to multiple generations of children born with prenatal opioid exposure.

2. Because of Defendants' horrific wrongdoing, which created the worst man-made epidemic in history, births of children with prenatal opioid exposure have increased exponentially since the onslaught of the opioid epidemic, and they show no signs of slowing down. As a result, our nations' public schools will be straddled with the extra costs of education of children with prenatal opioid exposure for years to come.

3. The opioid crisis has had a particularly profound impact on women, who are more likely than men to suffer from chronic pain, receive prescriptions for pain relievers and in higher doses, and use them for longer periods of time.[2] Women may become more dependent on

[2] *Opioid Addiction 2016 Facts & Figures,* American Society of Addiction Medicine, https://www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.

prescription pain relievers more quickly than men.[3] Prescription pain reliever overdose deaths among women increased more than 400% from 1999 to 2010, compared to 237% among men.[4] The rates of Neonatal Abstinence Syndrome (NAS), which occurs when a baby is born addicted to opioids as a result of use by the mother during pregnancy, have also increased dramatically.[5] Nationally, the cost of treating NAS increased from $61 million in 2003 to nearly $316 million in 2012.[6]

4. Plaintiffs bring this action on behalf of themselves and a national class of all public school districts that are independent units of government in the US. In the alternative, each Plaintiff brings this action on behalf of itself and a class of all public school districts in its state (jointly referred to unless otherwise specified as "the Class"). Plaintiffs and the Class bear the steadily rising costs of providing special education and related services to children who were exposed to opioid use *in utero*, making them more than twice as likely to exhibit learning and developmental disabilities than children who were not exposed.[7]

5. Plaintiffs and members of the Class also bear opioid-related costs associated with their workers' health expenses and insurance, including their workers' increased use of

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[3] *Id.*
[4] *Id.*
[5] Hannah Rappleye et al., *Born Addicted: The Number of Opioid-Addicted Babies is Soaring*, NBC News, Oct. 9, 2017, https://www.nbcnews.com/storyline/americas-heroin-epidemic/born-addicted-number-opioid-addicted-babies-soaring-n806346. *Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome*, Nat'l Inst. on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome (last updated Sept. 2015).
[6] T.E. Corr & C.S. Hollenbeak, *The economic burden of neonatal abstinence syndrome in the United States*, 112 Addiction 1590 (Sept. 2017), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1111/add.13842.
[7] Paul Morgan and Yangyang Wang, *The Opioid Epidemic, Neonatal Abstinence Syndrome, and Estimated Costs for Special Education Services*, 25 American Journal of Managed Care 13 (2019).

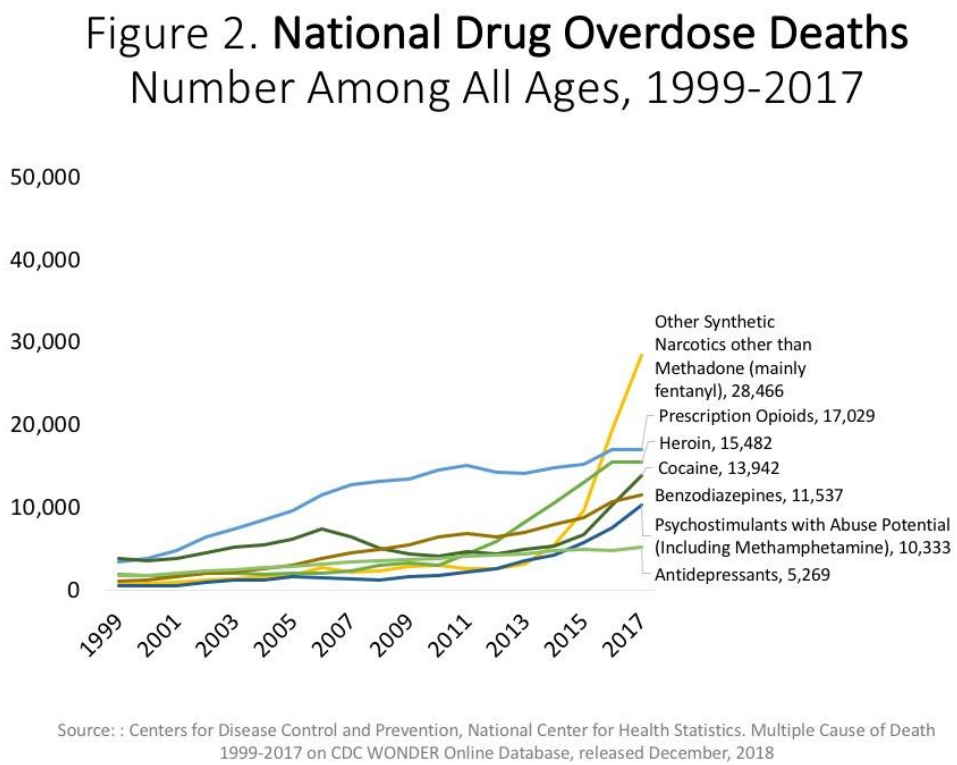
prescription opioids, and the treatments required as a result of their workers' opioid addictions, including treatment for overdoses and leaves of absences.

6. Plaintiffs and members of the proposed Class are frequently the first to identify a student in crisis, and the first point of contact for students who need support in the face of crisis. As a result, they have born costs for increased use of prescription opioids among students, including by providing resources to teachers and administrators who are on the front lines helping students, and by providing specialized health and/or counseling programs for opioid-addicted students. Even if the opioid crisis were abated today, Plaintiffs and members of the proposed Class will incur considerable costs in the years to come as the current cohort of adversely impacted children advance from lower school to high school with special needs all along the way.

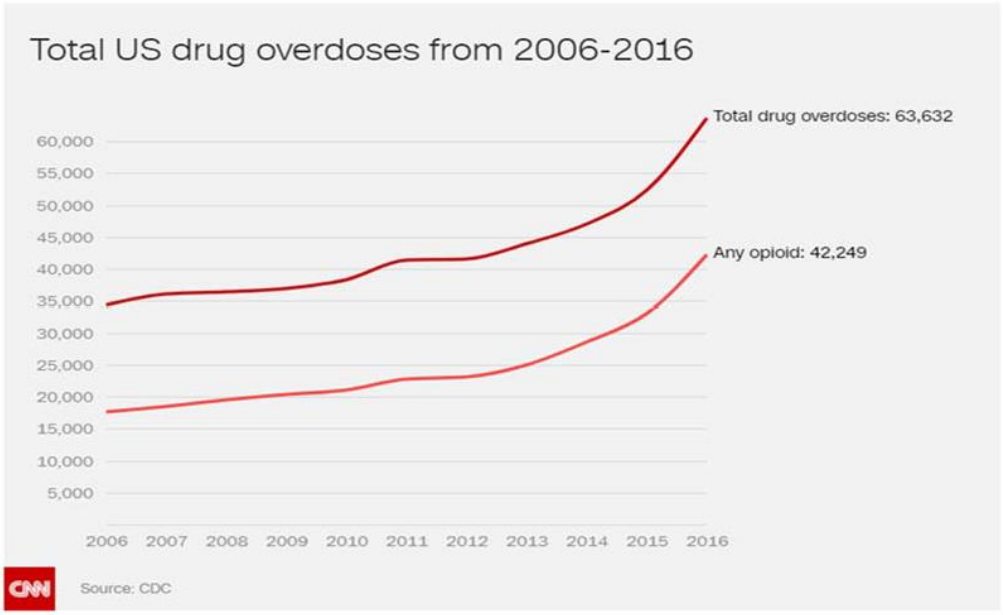
7. Public health officials have called the current opioid epidemic the worst drug crisis in American history.[8] On October 26, 2017, the President of the United States declared it a public health emergency. That year, opioid overdoses were responsible for more than 47,000 American deaths, and around 1.7 million people suffered from addiction related to prescription opioids.[9] According to recent estimates, as many as 130 people in the United States die every day from opioid overdoses, with as many as 35 percent of fatal overdoses involving prescription opioids.[10]

[8] Julie Bosman, *Inside a Killer Drug Epidemic: A Look at America's Opioid Crisis*, N.Y. Times (Jan. 6, 2017), https://www.nytimes.com/2017/01/06/us/opioid-crisis-epidemic.html.
[9] *Opioid Overdose Crisis*, NIH: National Institute on Drug Abuse (Jan. 2019), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#one.
[10] *Id.* Overdose Deaths Involving Prescription Opioids, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/data/prescribing/overdose-death-maps.html (last visited Sept. 19, 2019).

8. The following charts illustrate the rise of opioid-related overdose deaths in the United States:[11]

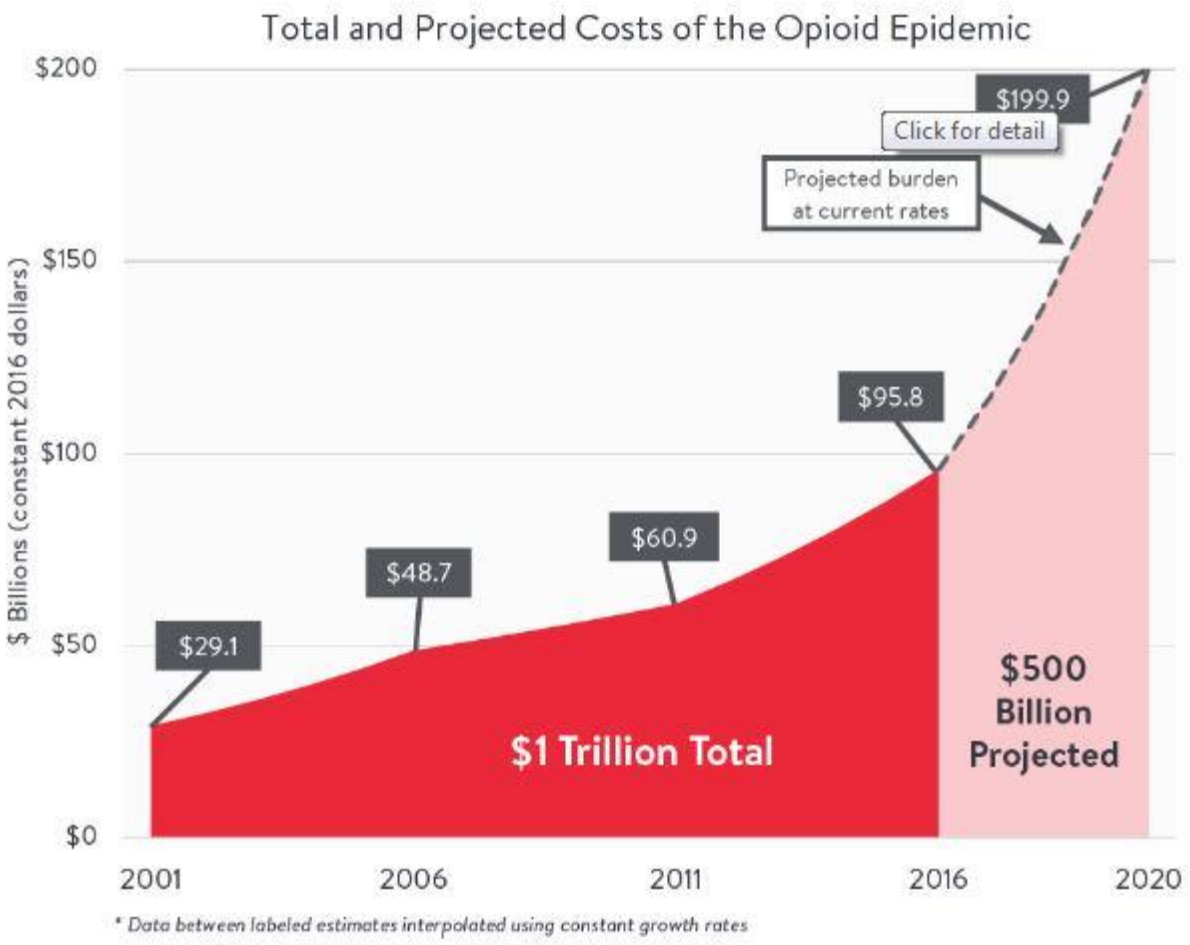


[11] *Overdose Death Rates*, National Institute of Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (hereinafter, "*Overdose Death Rates*") (last visited Dec. 14, 2018). *Opioids now kill more people than breast cancer*, CNN (Dec. 21, 2017), https://wtvr.com/2017/12/21/opioids-now-kill-more-people-than-breast-cancer/.

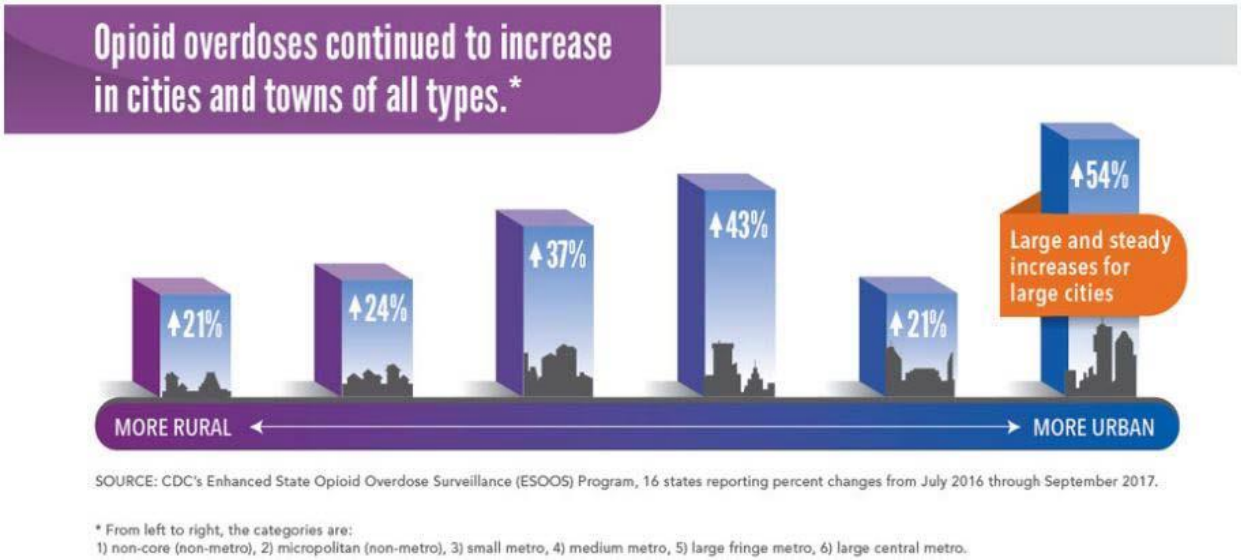


9. The opioid crisis and related expenses continue to grow. According to a report issued on February 13, 2018 by Altarum, a nonprofit health systems research and consulting organization, the cost of the country's opioid crisis is estimated to have exceeded $1 trillion from 2001 to 2017, and is projected to cost an additional $500 billion by 2020:[12]

[12] *Economic Toll Of Opioid Crisis In U.S. Exceeded $1 Trillion Since 2001*, Altarum (Feb. 13, 2018), https://altarum.org/news/economic-toll-opioid-crisis-us-exceeded-1-trillion-2001.



10. According to a Centers for Disease Control and Prevention ("CDC") report issued in March 2018, hospital emergency room visits for opioid overdoses rose 30% nationwide between July 2016 and September 2017. Over the same period, emergency room visits for opioid overdoses in large cities increased by 54%:



11. Drug manufacturers' deceptive marketing and sale of opioids to treat chronic pain is one of the main drivers of the opioid epidemic. Prescription opioids are powerful pain medications that historically have been used for short-term, post-surgical and trauma-related pain, and for palliative end-of-life care primarily in cancer patients. Because opioids are highly addictive and dangerous, the U.S. Food and Drug Administration ("FDA") regulates them as Schedule II Controlled Substances, a classification reserved for drugs that have a high potential for abuse and that may lead to severe psychological or physical dependence.

12. This demonstrated need for caution comports with the historical understanding of both the medical community and American culture at large regarding the serious consequences of opioid use and misuse. Opioids' powerful ability to relieve pain comes at a steep price; opioids are dangerously addictive and often lethal substances. For generations, physicians were taught that opioid painkillers were highly addictive and should be used sparingly and primarily for patients near death.[13] The medical community also understood that opioids were poorly suited

[13] Harriet Ryan et al., *OxyContin goes global – "We're only just getting started*," L.A. Times (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/ (hereinafter, "Ryan, *OxyContin goes global*").

for long-term use because tolerance would require escalating doses, and dependence would make it extremely difficult to discontinue their use.

13. The prevailing and accurate understanding of the enormous risks and limited benefits of long-term opioid use constrained drug manufacturers' ability to drive sales. In order to suppress reasonable concerns about opioids and to maximize profits, opioid manufacturers, including Coconspirators Insys, Mallinckrodt, Purdue, and the Sacklers (defined below in § II (C)),[14] and Defendants Janssen, Endo, Cephalon, and Actavis (individually defined in § II (B)) (collectively, the "Manufacturing Defendants") engaged in a concerted, coordinated strategy to recast the way in which doctors and patients think about pain and, specifically, to encourage the use of opioids to treat not just the relative few who suffer from such things as acute post-surgical pain and end-stage cancer pain, but the masses who suffer from common chronic pain conditions.

14. Borrowing from the tobacco industry's playbook, the Manufacturing Defendants employed ingenious marketing strategies, as detailed further herein, designed to "reeducate" the public and prescribers. The Manufacturing Defendants deliberately conceived these strategies to create, and in fact did create, an entirely new "health care" narrative – one in which opioids would be considered safe and effective for long-term use, and pain aggressively treated at all costs. According to this newly fabricated narrative, pain had been seriously under treated throughout the United States because opioids were under prescribed, and doctors came under enormous pressure to treat all kinds of pain with opioids.

[14] The Purdue Pharma, Mallinckrodt, and Insys entities are not listed as Defendants at this time because they filed bankruptcy. The Purdue Bankruptcy Court temporarily enjoined litigation against the Sacklers, so they are also not listed as Defendants at this time.

15. The Manufacturing Defendants' intention was to normalize aggressively prescribing opioids for numerous kinds of pain that had been treated without opioids by downplaying the very real and serious risks of opioids, especially the risk of addiction, and by misstating and exaggerating the benefits of their use. To accomplish this goal, they intentionally misled doctors and patients about the appropriate uses, risks, safety and efficacy of prescription opioids. They did so directly through sales representatives and marketing materials and indirectly through financial relationships with academic physicians, professional societies, hospitals, trade associations for state medical boards, and seemingly neutral third-party foundations.

16. False messages about the safety, addictiveness, and efficacy of opioids were disseminated by infiltrating professional medical societies and crafting and influencing industry guidelines in order to disseminate false and deceptive pro-opioid communiques under the guise of science and truth. According to a February 2018 report issued by U.S. Senator Claire McCaskill, opioid manufacturers, including several of the Manufacturing Defendants, paid nearly $9 million to advocacy groups and professional societies operating in the area of opioids policy between 2012 and 2017.[15] The manufacturers got their money's worth:

> Initiatives ***from the groups in this report often echoed and amplified messages favorable to increased opioid use*** – and ultimately, the financial interests of opioid manufacturers. ***These groups have issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids*** for chronic pain, lobbied to change laws directed at curbing opioid use, and argued against accountability for physicians and industry executives responsible for overprescription and misbranding.[16]

[15] *Fueling an Epidemic, Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Advocacy Groups*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1 (Feb. 13, 2018), https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf (hereinafter, "*February 2018 McCaskill Report*").

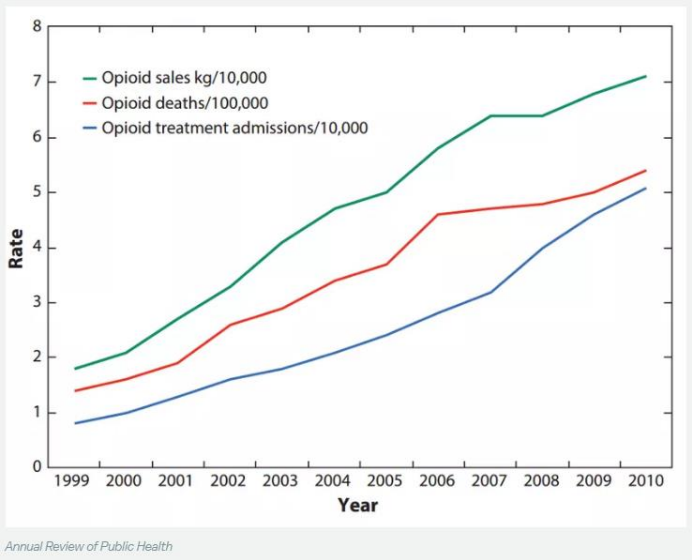
[16] Emphasis is added throughout unless otherwise noted.

17. When, in 2016, the CDC recommended limits on prescribing opioids for chronic pain, the purportedly neutral medical societies also strongly criticized those guidelines. Based on that and other similar conduct, the *February 2018 McCaskill Report* concluded there was "a direct link between corporate donations and the advancement of opioids-friendly messaging."

18. The Manufacturing Defendants falsely assured the public and prescribers that the risk of becoming addicted to prescription opioids, among patients being treated for pain, was less than 1%. In reality, many people with no addiction history can become addicted after just weeks or even days of use.[17] As many as 56% of patients receiving long-term prescription opioid painkillers become addicted.[18] Indeed, almost one in five people who receive an opioid prescription with a ten days' supply will still be taking opioids one year later.[19]

19. The Manufacturing Defendants' focus on driving opioid sales growth led to concomitant growth both in the deaths resulting from opioid use and in hospital admissions for opioid-related addiction treatment:[20]

[17] Anna Lembke, *Drug Dealer, MD: How Doctors Were Duped, Patients Got Hooked, and Why It's So Hard to Stop*, 22 (Johns Hopkins University Press 2016) (hereinafter, "Lembke (2016)").
[18] Bridget A. Martell et al., *Systematic Review: Opioid Treatment for Chronic Back Pain: Prevalence, Efficacy, and Association with Addiction*, 146(2) Ann. Intern. Med. 116-27 (2007), http://annals.org/aim/article/732048/systematic-review-opioid-treatment-chronic-back-painprevalence-efficacy-association (hereinafter, "Martell, *Systematic Review*").
[19] Sarah Frostenson, *The risk of a single 5-day opioid prescription, in one chart*, Vox (Mar. 18, 20107, 7:30 AM), www.vox.com/2017/3/18/14954626/one-simple-way-to-curb-opioidoveruse-prescribe-them-for-3-days-or-less.
[20] Andrew Kolodny et al., *The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction*, 36 Annu. Rev. Public Health 559-74 (2015), http://www.annualreviews.org/doi/pdf/10.1146/annurev-publhealth-031914-122957.



Put simply, the Manufacturing Defendants manipulated and misrepresented medical science to increase sales and profits—at great human cost.

20. In a study published on March 6, 2018 in the *Journal of the American Medical Association* ("*JAMA*"),[21] researchers conducting the first randomized clinical trial designed to compare the efficacy of opioids and non-opioids (including acetaminophen, ibuprofen and lidocaine) for the treatment of moderate to severe back pain, hip pain, and knee osteoarthritis pain concluded that patients who took opioids over the long term experienced no better improvement in pain-related function than patients who used safer alternatives.

21. Defendants McKesson, Cardinal Health and AmerisourceBergen (individually defined in § II (D)) (collectively, the "Distributor Defendants") are major distributors of controlled substances, acting as middlemen between drug companies and pharmacies. Like the Manufacturing Defendants, the Distributor Defendants were also aware of a growing epidemic of

[21] Erin E. Krebs et al., *Effect of Opioid vs. Nonopioid Medications on Pain-Related Function in Patients with Chronic Back Pain or Hip or Knee Osteoarthritis Pain, The SPACE Randomized Clinical Trial*, 319(9) JAMA 872-82 (2018) (hereinafter, "Krebs, *Effect of Opioid vs. Nonopioid Medications*").

addiction to, and abuse of, the prescription opioids they supplied. The Manufacturing Defendants and the Distributor Defendants were aware of the quantities and frequency with which those drugs were distributed nationwide. However, both the Manufacturing Defendants and the Distributor Defendants persisted in failing to report suspicious sales as required by state and federal law. Their failures to follow the law significantly contributed to rising addiction and overdose rates nationwide.

22. Recently released data on the sale of prescription pain pills shows the full extent of Defendants' scheme to saturate the market with opioid medications. The Drug Enforcement Administration (DEA) tracks the manufacturing and distribution of oxycodone and hydrocodone pills, which represent 75% of all opioid pill shipments distributed to pharmacies.[22] Between 2006 and 2014, more than 12 billion prescription opioid pills were supplied to Plaintiffs' states.

23. Distributor Defendants McKesson, Cardinal Health, and AmerisourceBergen were key players in the spread of opioid pain relievers, responsible for 44% of the country's supply of prescription pain pills. Marketing Defendant Actavis Pharma manufactured 34.5% of the opioids distributed nationwide, and Purdue Pharma was responsible for an additional 3.3% of the market.

24. The production and distribution of massive quantities of prescription pain pills was not an accident. Defendants' decision to ignore red flags, and their consistent failure to report suspicious orders, created a market flooded with prescription opioids. From 2006 to 2012, the volume of opioid pills handled by the 10 largest companies increased by 51%. During this

[22] The following statistics are available through the *Washington Post*'s interactive DEA pain pill database. *Drilling into the DEA's pain pill database,* The Washington Post (Updated July 21, 2019), https://www.washingtonpost.com/graphics/2019/investigations/dea-pain-pill-database/.

time, there were 36 opioid pills for every person in the country, and nationwide sales of prescription opioid pain pills increased from $6.1 billion to $8.5 billion.[23]

25. The country's major opioid distributors have paid hefty fines for their failures to report suspicious orders of opioids as required by law. McKesson, the largest prescription drug wholesale company in the United States, agreed on January 17, 2017, to pay a $150 million fine to the federal government. In December 2016, Cardinal Health reached a $44 million settlement with the federal government. One month later, Cardinal Health reached a $20 million settlement with the State of West Virginia. AmerisourceBergen agreed to pay West Virginia $16 million in 2017.[24] As of 2019, corporations have paid almost $500 million in fines to the Justice Department for "failing to report and prevent suspicious [opioid] drug orders."[25]

26. These fines, however, are dwarfed by Defendants' profits from their scheme. According to *Fortune* magazine, McKesson, AmerisourceBergen and Cardinal Health are each among the top 15 companies in the Fortune 500. The Sackler family[26] owns Purdue Pharma, LP – a privately held company which would be named as a defendant herein were it not for the automatic stay triggered by its 2019 bankruptcy filing. The Sackler family is listed on *Fortune*'s

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[23] Scott Higham et al., *76 billion opioid pills: Newly released federal data unmasks the epidemic*, The Washington Post (July 16, 2019), https://www.washingtonpost.com/investigations/76-billion-opioid-pills-newly-released-federal-data-unmasks-the-epidemic/2019/07/16/5f29fd62-a73e-11e9-86dd-d7f0e60391e9_story.html (hereinafter, "Higham et al., *76 billion opioid pills*").
[24] Nate Raymond, *McKesson to pay $37 million to resolve West Virginia opioid lawsuit*, Reuters (May 2, 2019), https://www.reuters.com/article/us-usa-opioids-litigation/mckesson-to-pay-37-million-to-resolve-west-virginia-opioid-lawsuit-idUSKCN1S81HO; Press Release, U.S. Department of Justice, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act (Dec. 23, 2016), https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.
[25] Higham et al., *76 billion opioid pills, supra* n.23.
[26] Including co-conspirators RICHARD S. SACKLER, JONATHAN D. SACKLER, MORTIMER D.A. SACKLER, KATHE A. SACKLER, ILENE SACKLER LEFCOURT, BEVERLY SACKLER, THERESA SACKLER, DAVID A. SACKLER, TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER FAMILY (collectively, "the Sacklers").

list of America's wealthiest families. The Sacklers caused Purdue to engage in "ruthless marketing of painkillers has generated billions of dollars – and millions of addicts."[27]

27. The impact of opioid addiction has devastated the nation. Former FDA Commissioner David A. Kessler has called the failure to recognize the dangers of painkillers "one of the greatest mistakes of modern medicine." As alleged herein, that "mistake" was not a mistake at all. Instead, it directly resulted in large part from Defendants' false and misleading messaging, which was carefully calculated to reach as many prescribers as possible, as well as Defendants' willingness to turn a blind eye to suspicious orders.

28. Even when some defendants were forced to admit the unlawful marketing and sale of opioids and/or the failure to report suspicious orders, the conduct did not abate because profits realized by the aggressive marketing and prescribing of opioids dwarf the penalties imposed as a result of violations found. The fines were absorbed as part of the overhead for engaging in this lawless and immoral behavior as the incentive to push opioids remained. The scheme was so financially successful, in fact, that despite the clear and obvious devastation it caused in the U.S., Purdue's owners, the Sacklers, continue to pursue the same strategy abroad. As reported by the *Los Angeles Times* in 2016, Purdue stated "[w]e're only just getting started." At that time, Purdue intended to "[p]ut the painkiller that set off the United States opioid crisis into medicine cabinets around the world. A network of international companies owned by the family is moving rapidly into Latin America, Asia, the Middle East, Africa and other regions, and pushing for broad use of painkillers in places ill-prepared to deal with the ravages of opioid abuse and addiction."[28]

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[27] Patrick Radden Keefe, *The Family that Built an Empire of Pain*, The New Yorker (Oct. 30, 2017) (hereinafter, "Keefe, Empire of Pain"), https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain.
[28] Ryan, *OxyContin goes global*, *supra* n.13.

29. While great attention has been paid to the strain placed on states and local governments for their vast public health expenditures to respond to the opioid epidemic, the astounding harm caused to our nation's public schools has gone largely unnoticed. Children born with opioid exposure *in utero* are tragic victims of the opioid epidemic, and they suffer from a host of developmental and behavioral problems for the rest of their lives. Public schools are tasked with finding the resources to provide special support and education to these children.

30. In addition, public schools are the country's largest public employer, and most of them provide health insurance and other benefits to their employees. Thus, public schools have footed the bills for their employees' prescription opioids—including those prescribed inappropriately—and for the resulting healthcare costs, including addiction treatment and workers' compensation.

II. PARTIES.

A. Plaintiffs.

31. Plaintiffs bring this civil action against Defendants on behalf of themselves and other similarly-situated public school districts to recoup monies they have spent because of Defendants' false, deceptive, and/or unfair marketing and unlawful distribution of dangerous prescription opioids in violation of federal and state law, to eliminate the hazard to public health and safety caused by the Defendants' continuous operation of a criminal enterprise to market opioids, and to abate the resulting nuisance.

32. Board of Education of Rochester City School District is located in Rochester, New York.

33. Board of Education of Minnetonka School District No. 276 is located in Minnetonka, Minnesota.

34. Board of Education of Mason County Public Schools is located in Point Pleasant, West Virginia.

35. Baltimore City Board of School Commissioners is located in Baltimore, Maryland.

Illinois Public Schools

36. Board of Education of East Aurora, School District 131, is located in East Aurora, Illinois.

37. Board of Education of Thornton Township High Schools, District 205, is located in South Holland, Illinois.

38. Board of Education of Thornton Fractional Township High Schools, District 215, is located in Calumet City, Illinois.

39. Board of Education of Joliet Township High School, District 204, is located in Joliet, Illinois.

Kentucky Public Schools

40. Board of Education of Fayette County Public Schools is located in Lexington, Kentucky.

41. Board of Education of LaRue County Public Schools is located in Hodgenville, Kentucky.

42. Board of Education of Bullitt County Public Schools is located in Shepherdsville, Kentucky.

43. Board of Education of Breathitt County Public Schools is located in Jackson, Kentucky.

44. Board of Education of Estill County Public Schools is located in Irvine, Kentucky.

45. Board of Education of Harrison County Public Schools is located in Cynthiana, Kentucky.

46. Board of Education of Hart County Public Schools is located in Munfordville, Kentucky.

47. Board of Education of Jefferson County Public Schools is located in Louisville, Kentucky.

48. Board of Education of Johnson County Public School District is located in Paintsville, Kentucky.

49. Board of Education of Lawrence County Public Schools is located in Louisa, Kentucky.

50. Board of Education of Martin County Public Schools is located in Inez, Kentucky.

51. Board of Education of Menifee County Public Schools is located in Frenchburg, Kentucky.

52. Board of Education of Owsley County Public Schools is located in Bonneville, Kentucky.

53. Board of Education of Wolfe County Public Schools is located in Campton, Kentucky.

Maine Public Schools

54. Board of Education of Bangor School Department is located in Bangor, Maine.

55. Board of Education of Cape Elizabeth School Department is located in Cape Elizabeth, Maine.

56. Board of Education of Maine Regional School Unit ("RSU") 10 is located in Rumworth, Maine.

57. Board of Education of Maine RSU 13 is located in Rockland, Maine.

58. Board of Education of Maine RSU 25 is located in Bucksport, Maine

59. Board of Education of Maine RSU 26 is located in Orono, Maine.

60. Board of Education of Maine RSU 29 is located in Houlton, Maine.

61. Board of Education of Maine RSU 34 is located in Old Town, Maine

62. Board of Education of Maine RSU 40 is located in Union, Maine.

63. Board of Education of Maine RSU 50 is located in Dyer Brook, Maine.

64. Board of Education of Maine RSU 57 is located in Waterboro, Maine.

65. Board of Education of Maine RSU 60 is located in North Berwick, Maine.

66. Board of Education of Maine RSU 71 is located in Belfast, Maine.

67. Board of Education of Maine RSU 9 is located in Farmington, Maine.

68. Board of Education of Maine School Administrative District ("SAD") 11 is located in Gardiner, Maine.

69. Board of Education of Maine SAD 15 is located in Cumberland, Maine

70. Board of Education of Maine SAD 28/Five Town Central School District is located in Camden, Maine.

71. Board of Education of Maine SAD 35 is located in Eliot, Maine.

72. Board of Education of Maine SAD 44 is located in Bethel, Maine.

73. Board of Education of Maine SAD 53 is located in Pittsfield, Maine.

74. Board of Education of Maine SAD 55 is located in Hiram, Maine.

75. Board of Education of Maine SAD 6 is located in Buxton, Maine.

76. Board of Education of Maine SAD 61 is located in Bridgton, Maine.

77. Board of Education of Maine SAD 72 is located in Fryeburg, Maine.

78. Board of Education of Portland School Department is located in Portland, Maine.

79. Board of Education of Scarborough School Department is located in Scarborough, Maine.

80. Board of Education of South Portland School Department is located in South Portland, Maine.

81. Board of Education of St. George Municipal School District is located in St. George, Maine.

82. Board of Education of Waterville School Department is located in Waterville, Maine.

83. The Board of Education of Ellsworth School Department is located in Ellsworth, Maine.

New Hampshire Public Schools

84. Board of Education of Goshen School District is located in Goshen, New Hampshire.

85. Board of Education of Kearsarge RSU-School Administrative Unit 65 is located in New London, New Hampshire

86. Board of Education of Lebanon School District is located in Lebanon, New Hampshire.

87. Board of Education of Pittsfield School District is located in Pittsfield, New Hampshire.

88. Board of Education of Tamworth School District is located in Tamworth, New Hampshire.

89. Plaintiffs directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which Plaintiffs seek relief. Plaintiffs' past and continuing sustained damages include, but are not limited to: (1) costs associated with special education and related programs, including, but not limited to, special programs for children with learning disabilities related to *in utero* opioid exposure, or for children in need of psychological counseling due to opioid-related family crisis; (2) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; and (3) costs associated with increased school security in all facilities of the school board district; (4) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for covered patients suffering from opioid-related addiction or disease, including overdoses; (5) costs associated with increased healthcare and healthcare insurance for school district employees and their families; and (6) costs of disability payments. These damages have been suffered and continue to be suffered directly by Plaintiffs and are trebled as a matter of law.

90. Plaintiffs also seek the means to abate the epidemic created by Defendants' wrongful and unlawful conduct. Plaintiffs are authorized by law to abate any nuisance and prosecute (in any court of competent jurisdiction) any person who creates, continues, contributes to, or suffers such nuisance to exist, as well as to prevent injury and annoyance from such nuisance.

B. Manufacturing Defendants.

91. Defendant Cephalon, Inc. is a Delaware corporation with its headquarters and principal place of business in Frazer, Pennsylvania. In October 2011, Cephalon, Inc. was

acquired by Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), which is incorporated under the laws of Israel, with its principal place of business in Petah Tikva, Israel. Since Teva Ltd. acquired Cephalon, Inc., its United States sales and marketing activities have been conducted by defendant Teva Pharmaceuticals USA, Inc. ("Teva USA" and, together with Teva Ltd., "Teva"), a wholly owned operating subsidiary of Teva Ltd. Teva USA's headquarters and principal place of business are in North Wales, Pennsylvania. Cephalon, Inc. and Teva are collectively referred to herein as "Cephalon."

92. Defendant Endo International plc is an Irish public limited company with its headquarters in Dublin, Ireland. Defendant Endo Health Solutions Inc. is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Defendant Endo Pharmaceuticals Inc. (together with Endo International plc and Endo Health Solutions Inc., "Endo") is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is an indirectly, wholly owned subsidiary of Endo International plc.

93. Defendant Janssen Pharmaceuticals, Inc. ("Janssen")—which was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which, in turn, was formerly known as Janssen Pharmaceutica, Inc.—is a Pennsylvania corporation headquartered in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly-owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

94. Defendant Johnson & Johnson, Inc. is a New Jersey corporation that is headquartered in New Brunswick, New Jersey.

95. Defendant Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis plc acquired Allergan plc in 2015, and

the combined company changed its name to Allergan plc. Defendant Actavis, Inc. was acquired by Defendant Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013, then to Actavis plc in October 2013.

96. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly owned subsidiary of Allergan plc (f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.).

97. Defendant Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

98. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey.

99. Each of the defendants and entities in paragraphs 97, 98, and 99 is owned by Defendant Allergan plc, which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities are referred to as "Actavis."

C. Distributor Defendants.

100. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation with its headquarters and principal place of business in Chesterbrook, Pennsylvania.

101. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio corporation with its headquarters and principal place of business in Dublin, Ohio.

102. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters and principal place of business in San Francisco, California.

D. National Retail Pharmacies.

a) CVS

103. Defendant CVS Health Corporation ("CVS Health") is a Delaware Corporation with its principal place of business in Rhode Island. Through its various DEA registrant subsidiaries and affiliated entities, CVS Health conducts business as a licensed wholesale distributor and pharmacy operator. At all times relevant to this Complaint, CVS Health distributed prescription opioids throughout the United States.

104. Defendant CVS Indiana L.L.C. is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Defendant CVS Rx Services, Inc. is a New York corporation with its principal place of business in Chemung, New York. Defendant CVS TN Distribution, LLC is a Tennessee corporation with its principal place of business in Knoxville, Tennessee.

105. Defendant CVS Pharmacy, Inc. is a Rhode Island corporation with its principal place of business in Woonsocket, Rhode Island. CVS Pharmacy, Inc. is a wholly owned subsidiary of CVS Health. Defendant CVS Pharmacy, Inc. is both a DEA registered "distributor"[29] and a DEA registered "dispenser"[30] of prescription opioids.

106. Defendant Omnicare Distribution Center LLC is a Delaware corporation with its principal place of business in Ohio. Omnicare Distribution Center LLC, a CVS Health company, portrays itself as an industry leading long-term care pharmacy services provider focused on supporting assisted living community residents.

107. Defendants CVS Health Corporation; CVS Indiana L.L.C.; CVS Rx Services, Inc.; CVS TN Distribution, LLC; CVS Pharmacy, Inc.; and Omnicare Distribution Center, LLC are collectively referred to as "CVS." CVS conducts business as a licensed wholesale distributor

[29] 21 U.S.C. § 802(11) and § 822(a)(1).
[30] 21 U.S.C. § 802(1) and § 822(a)(2).

and dispenser. At all times relevant to this Complaint, CVS distributed and/or dispensed prescription opioids throughout the United States.

b) Walgreens

108. Defendant Walgreen Co., an Illinois corporation with its principal place of business in Illinois, acted as a retail pharmacy in the United States, until Walgreen Co. completed the acquisition of Alliance Boots, a British pharmacy giant, in 2014. After this acquisition, the company simply became Walgreens Boots Alliance, Inc.

109. Defendant Walgreens Boots Alliance, Inc. is a Delaware corporation with its principal place of business in Illinois. Walgreens Boots Alliance, Inc. describes itself as the successor of Walgreen Co.

110. Defendant Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, Illinois. Walgreen Eastern Co., Inc. is a subsidiary of Walgreens Boots Alliance, Inc.

111. Defendants Walgreens Boots Alliance, Inc.; Walgreen Co.; and Walgreen Eastern Co., Inc. are collectively referred to as "Walgreens."

112. Through its various DEA registrant subsidiaries and affiliated entities, Walgreens conducted and conducts business as a licensed wholesale distributor and pharmacy operator. At all times relevant to this Complaint, Walgreens distributed and sold prescription opioids throughout the United States.

113. Expanding its chain pharmacy operations, Walgreens also acquired a number of former Rite Aid stores. Walgreens is liable as a successor for these stores' prior conduct, as well as for its own operations.

c) Walmart

114. Defendant Walmart Inc. ("Walmart"), formerly known as Wal-Mart Stores, Inc., is a Delaware corporation with its principal place of business in Bentonville, Arkansas.

115. Defendant Wal-Mart Stores East, LP is a Delaware limited partnership with its principle place of business in Arkansas.

116. Defendant WSE Management, LLC, is a Delaware limited liability company and owns one percent of Wal-Mart Stores East, LP.

117. Defendant WSE Investment, LLC, is a Delaware limited liability company, and owns ninety-nine percent of Wal-Mart Stores East, LP.

118. The sole owner of both WSE Management, LLC and WSE Investment, LLC is Wal-Mart Stores East Inc., an Arkansas corporation.

119. The sole shareholder of Wal-Mart Stores East, Inc. is Walmart Inc., f/k/a Wal-Mart Stores, Inc.

120. Defendants Walmart Inc., f/k/a Wal-Mart Stores, Inc.; Wal-Mart Stores East, LP; WSE Management, LLC; WSE Investment, LLC; and Wal-Mart Stores East, Inc. are collectively referred to as "Walmart."

121. Through its various DEA registrant subsidiaries and affiliated entities, Walmart conducts business as a licensed wholesale distributor and pharmacy operator. At all times relevant to this Complaint, Walmart distributed prescription opioids throughout the United States.

d) Rite Aid

122. Rite Aid Corporation is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

123. Defendant Rite Aid Hdqtrs. Corp. is a Delaware corporation with its principal office located in Camp Hill, Pennsylvania. Defendant Rite Aid Hdqtrs. Corp. and Defendant Rite Aid Corporation, by and through their various DEA registrant subsidiaries and affiliated entities, conduct business as licensed wholesale distributors and pharmacy operators.

124. Defendant Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. is a subsidiary of Rite Aid Corporation and is itself a Maryland corporation with its principal office located in Camp Hill, Pennsylvania.

125. Defendant Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center is a subsidiary of Rite Aid Corporation and is itself a Delaware corporation with its principal office located in Camp Hill, Pennsylvania.

126. Defendants Rite Aid Corporation; Rite Aid Hdqtrs. Corp.; Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc.; Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center are collectively referred to as "Rite Aid."

127. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. Rite Aid also operates retail stores, including in and around Plaintiffs' geographical area that sell prescription medicines, including opioids.

128. At all times relevant to this Complaint, Rite Aid of Maryland, Inc. d/b/a Rite Aid Mid-Atlantic Customer Support Center, Inc. and Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center distributed prescription opioids throughout the United States.

129. Collectively, CVS, Walgreens, Walmart, and Rite Aid are referred to as "National Retail Pharmacies" or "Retail Pharmacy Defendants."

E. Unnamed Co-Conspirators.

130. Purdue Pharma L.P. is a Delaware limited partnership formed in 1991 with headquarters in Stamford, Connecticut. The company maintains four operational branches: Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P. and Purdue Products L.P. Rhodes Pharmaceuticals L.P. ("Rhodes") is a Delaware limited partnership formed in or around 2007 with headquarters in Coventry, Rhode Island. Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P., Purdue Products L.P. and Rhodes are referred to collectively herein as "Purdue." Purdue filed for bankruptcy in September 2019 and therefore is not named as a Defendant at this time.

131. Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt LLC (together with Mallinckrodt plc, "Mallinckrodt") is a Delaware limited liability company with its headquarters in Hazelwood, Missouri. Mallinckrodt filed for bankruptcy in October 2020 and therefore is not named as a Defendant at this time.

132. Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its principal place of business in Chandler, Arizona. Insys filed for bankruptcy in June 2019 and therefore is not named as a Defendant at this time.

133. Richard S. Sackler is a natural person residing in Travis County, Texas. He served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

134. Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

135. Mortimer D.A. Sackler is a natural person residing in New York County, New York. He served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

136. Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

137. Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She served as a member of the Board of Directors of Purdue and Purdue-related entities since from the 1990s until approximately 2017-2019.

138. Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

139. Theresa Sackler is a natural person residing in New York County, New York. She served as a member of the Board of Directors of Purdue and Purdue-related entities from the 1990s until 2018.

140. David A. Sackler is a natural person residing in New York County, New York. He served as a member of the Board of Directors of Purdue and Purdue-related entities from 2012 until approximately 2018.

141. Trust for the Benefit of Members of the Raymond Sackler Family (the "Raymond Sackler Trust") is a trust for which Beverly Sackler, Richard S. Sackler or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

142. Collectively, the co-conspirators listed in ¶¶ 133-141 are referred to as the "Sacklers." The U.S. Bankruptcy Court *In re: Purdue Pharma, L.P., et al*., 19-23649 (Bankr. S.D.N.Y.) ordered a temporary injunction to litigation against the Sacklers until at least March 2021. Therefore, the Sacklers are not named as Defendants at this time.

III. JURISDICTION AND VENUE.

143. This Court has jurisdiction over Plaintiffs' claims for the purposes of pretrial proceedings pursuant to 28 U.S.C. §1407.[31]

144. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, based on Defendants' violations of federal law, specifically 18 U.S.C. § 1961, *et seq.* ("Racketeer Influenced and Corrupt Organizations Act" or "RICO"), 18 U.S.C. § 1965 pertaining to RICO jurisdiction, and supplemental jurisdiction over the state law claims set forth below pursuant to 28 § 1367, because those state law claims are so related to Plaintiffs' federal claims that they form part of the same case or controversy.

145. The U.S. District Court for the Northern District of Illinois has personal jurisdiction over Defendants, because they conduct business in Illinois, purposefully direct or directed their actions toward Illinois, and have the requisite minimum contacts with Illinois necessary to constitutionally permit this Court to exercise jurisdiction. That Court also has personal jurisdiction over all Defendants under 18 U.S.C. 1965(b). That Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service, and Plaintiffs demonstrate national contacts. Here, the interests of justice require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the court in

[31] *See* Case Management Order One, ¶ 6.a., Dkt. 232 ("In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal districts, any Plaintiff whose case would be subject to transfer to these MDL proceedings may file its case directly in this District").

a single trial. Moreover, Defendants' actions and/or inactions described herein were purposefully directed at and/or within each of Plaintiffs' states, the damages were sustained by Plaintiffs and the Class within their states, and the damages sustained by Plaintiffs and the Class were a result of Defendants' actions and/or inactions, as described herein.

146. Venue in the Northern District of Illinois is proper, as various Defendants herein are registered to do business in the judicial district in which this matter is filed, may be served in this judicial district, conduct the business activities described herein in this judicial district, and various actions and/or inactions sued upon occurred in this judicial district. 18 U.S.C. § 1965(a); 28 U.S.C. §1391(b)(2).

IV. FACTUAL ALLEGATIONS.

A. Prescription Opioids.

147. The term opioid refers to (a) all drugs derived in whole or in part from the morphine-containing opium poppy plant such as morphine, laudanum, codeine, thebaine, hydrocodone, oxycodone and oxymorphone, and (b) synthetic opioids like fentanyl or methadone.

148. Opioids are derived from or possess properties similar to opium and heroin and, as such, they are highly addictive and dangerous and therefore are regulated by the federal government as controlled substances.

149. Since passage of the Controlled Substances Act ("CSA") in 1970, 21 U.S.C. § 801, *et seq.*, controlled substances have been categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the highest.[32] Opioids are generally categorized as Schedule II or Schedule III drugs. Schedule II drugs have "a high potential for abuse," and

[32] Schedule I drugs are defined by the CSA as drugs with no currently accepted medical use and a high potential for abuse.

"may lead to severe psychological or physical dependence."[33] Schedule II drugs may not be dispensed without an original copy of a manually signed prescription, which may not be refilled, from a doctor and filled by a pharmacist who both must be licensed by their state and registered with the DEA.[34] The labels for scheduled opioid drugs carry black box warnings of potential addiction, abuse, and misuse, including "[s]erious, life-threatening, or fatal respiratory depression." [35]

150. When under the continuous influence of opioids over time, patients grow tolerant to their analgesic effects. As tolerance increases, a patient typically requires progressively higher doses to obtain the same levels of pain reduction to which he has become accustomed – up to and including doses that are "frighteningly high."[36] At higher doses, the effects of withdrawal are more substantial, thus leaving a patient at a much higher risk of addiction. A patient can take the opioids at the continuously escalating dosages to match pain tolerance and still overdose at recommended levels. Studies on opioid use have demonstrated a correlation between high opioid dosage and poor physical function, as well as worsened overall general health.[37] Opioid use also delays injury recovery and increases the risk of permanent disability. In a study of Workers Compensation claims for lower back pain, increasing a patient's opioid dosage was found to correlate with an increasing risk of disability compared to non-opioid users.[38] Another study

[33] 21 U.S.C. § 812(b)(2).
[34] 21 U.S.C. § 829.
[35] *See, e.g.*, March 22, 2016, Required Safety Labeling Language for Immediate Release Opioids, FDA, https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM491594.pdf.
[36] M. Katz, *Long-term Opioid Treatment of Nonmalignant Pain: A Believer Loses His Faith*, 170 ARCHIVES OF INTERNAL MED. 1422 (2010).
[37] Kathryn Sullivan Dillie, et al., Quality of Life Associated With Daily Opioid Therapy in a Primary Care Chronic Pain Sample, 21 J. of the Am. Bd. Of Fam. Med. 108 (2008).
[38] Donald Teater, *The Psychological and Physical Side Effects of Pain Medications*, Nat. Safety Council (2016) (citing Barbara S. Webster, et al., *Relationship Between Early Opioid*

showed that prescribing opioids within six weeks of an injury actually *doubled* the risks of disability one year later.[39] Likewise, studies on opioid use prior to back surgery show poorer outcomes for patients—including increased pain, decreased function, and increased depression.[40]

151. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, all of which may persist for months after a complete withdrawal from opioids, depending on how long the opioids were used.

152. During much of the latter half of the 20th century, doctors used opioid pain relievers sparingly, and only in the short term, for cases of acute injury or illness, during and immediately after surgery, or for palliative cancer and end-of-life care.

153. Beginning in the late 20th century, however, and continuing through today, the Defendants acted to dramatically expand the marketplace for opioids. The market for short-term pain relief is significantly more limited than the market for long-term chronic pain relief. Defendants recognized that if they could sell opioids, not just for short-term pain relief but also for long-term chronic pain relief, they could achieve blockbuster levels of sales and dramatically increase their profits. They further recognized that if they could cause their customers to become physically addicted to their drugs, they would increase the likelihood that their blockbuster profits would continue indefinitely.

Prescribing for Acute Occupation Low Back Pain and Disability Duration, Medical Costs, Subsequent Surgery, and Late Opioid Use, 32 Spine 2127 (Sept. 2007)).

[39] Teater, *supra* n.38, (citing Gary M. Franklin, et al., *Early Opioid Prescription and Subsequent Disability Among Workers With Back Injuries: the Disability Risk Identtification Study Cohort*, 33 Spine 199 (2008)).

[40] Teater, *supra* n.38, (citing Sheyan J. Armaghani, et al., *Preoperative Opioid Use as a Predictor of Adverse Postoperative Self-Reported Outcomes in Patients Undergoing Spine Surgery*, 96 J. Bone & Joint Surgery (American) e89 (2014)).

B. Over the Course of More Than Two Decades, the Manufacturing Defendants Misled the Public Regarding the Dangers of Opioid Addiction and the Efficacy of Opioids for Long-Term Use, Causing Sales and Overdose Rates to Soar.

154. From the mid-90s to the present, the Manufacturing Defendants aggressively marketed and falsely promoted liberal opioid prescribing as presenting little to no risk of addiction, even when used long term for chronic pain. They infiltrated academic medicine and regulatory agencies to convince doctors that treating chronic pain with long-term opioids was evidence-based medicine when, in fact, they knew it was not. Huge profits resulted from these efforts, as did the present addiction and overdose crisis that has ravaged the nation.

1. Background on Opioid Overprescribing.

155. The Manufacturing Defendants' scheme to drive their rapid and dramatic expansion of prescription opioids was rooted in two pieces of so-called "evidence." The first was the publication of a 5-sentence, 100-word letter to the editor published in 1980 in the *New England Journal of Medicine* ("1980 Letter to the Editor").[41]

> [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North

[41] This very brief Letter to the Editor by Jane Porter ("Porter") and Dr. Herschel Jick ("Jick"), reported that less than 1% of patients at Boston University Medical Center who received narcotics while hospitalized became addicted. Jane Porter & Hershel Jick, *Addiction rate in patients treated with narcotics*, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980). However, the letter did not support the conclusion that opioids were safe for long-term treatment of chronic pain, the conclusion for which it was often cited by the industry. Harrison Jacobs, *This one-paragraph letter was used to launch the opioid epidemic*, Bus. Insider (May 26, 2016), http://www.businessinsider.com/porter-and-jick-letter-launched-the-opioid-epidemic-2016-5 (hereinafter, "Jacobs, *One-paragraph letter*"). As discussed in a 2009 article in the *American Journal of Public Health*, the 1980 Letter to the Editor "shed[] some light on the risk of addiction for acute pain, [but did] not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. [Indeed, t]here are a number of studies . . . that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse." Art Van Zee, *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am. J. Pub. Health 221-27 (Feb. 2009) (hereinafter, "Van Zee, *Promotion and Marketing*").

> American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy.[42]

156. The second piece of "evidence" was a single medical study published by Drs. Russell Portenoy ("Portenoy") and Kathleen Foley ("Foley") ("Portenoy Publication").[43] Portenoy emerged as one of the industry's most vocal proponents of long-term opioid use. He essentially made it his life's work to campaign for the movement to increase use of prescription opioids. He was one of Big Pharma's[44] "thought leaders" and was paid to travel the country to promote more liberal opioid prescribing for many types of pain. His talks were sponsored by the Manufacturing Defendants and organizations paid by them, under the guise of continuing medical education ("CME") programs for doctors. Portenoy was a paid propagandist for Big Pharma, withfinancial relationships with at least a dozen pharmaceutical companies, most of which produced prescription opioids.[45]

157. On November 1, 2017, the President's Commission on Combating Drug Addiction and the Opioid Crisis noted the important and detrimental role played by the 1980

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[42] German Lopez, *A 5-sentence letter helped trigger America's deadliest drug overdose crisis ever*, Vox (June 1, 2017), https://www.vox.com/science-and-health/2017/6/1/15723034/opioidepidemic- letter-1980-study.

[43] In 1986, the medical journal *Pain*, which would eventually become the official journal of the American Pain Society ("APS"), published an article by Portenoy and Foley summarizing the results of a "study" of 38 chronic non-cancer pain patients who had been treated with opioid painkillers. Portenoy and Foley concluded that, for non-cancer pain, opioids "can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioid abuse." However, their study was neither scientific nor did it meet the rigorous standards commonly used to evaluate the validity and strength of such studies in the medical community. For instance, there was no placebo control group, and the results were retroactive (asking patients to describe prior experiences with opioid treatment rather than less biased, in-the-moment reports). The authors themselves advised caution, stating that the drugs should be used as an "alternative therapy" and recognizing that longer-term studies of patients on opioids would have to be performed. None were. *See* Lembke (2016), supra n.17 at 59-62.

[44] "Big Pharma" is used herein to refer to large pharmaceutical companies, including, but not limited to, Defendants, considered especially as a politically influential group.

[45] Lembke (2016), *supra* n.17, at 59 (citing Barry Meier, *Pain Killer: A "Wonder" Drug's Trail of Addiction and Death* (St. Martin's Press, 1st ed. 2003)).

Letter to the Editor and the Portenoy Publication, in a section of the Commission's Report with the header "Contributors to the Current Crisis."[46]

158. Portenoy has now admitted that he intentionally minimized the risks of opioids.[47] In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not "real" and left real evidence behind:

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, ***none of which represented real evidence***, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. ***In essence this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind***.[48]

159. The damage, however, was already done. The Manufacturing Defendants used the 1980 Letter to the Editor and the Portenoy Publication as the foundation for a massive, far-reaching campaign to dramatically recast the thinking of healthcare providers, patients, policymakers and the public on the risk of addiction presented by opioid therapy. By 1997, the American Pain Society ("APS") and the American Academy of Pain Medicine ("AAPM") (both funded by the Manufacturing Defendants) issued a "landmark consensus," co-authored by Portenoy, stating that there was little risk of addiction or overdose for pain patients.[49]

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[46] *The President's Commission on Combating Drug Addiction and the Opioid Crisis* at 20 (Nov. 1, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.

[47] Celine Gounder, *Who Is Responsible for the Pain-Pill Epidemic?*, New Yorker (Nov. 8, 2013), http://www.newyorker.com/business/currency/who-is-responsible-for-the-pain-pill-epidemic (hereinafter, "Gounder, *Who Is Responsible*").

[48] Jacobs, *One-paragraph letter*, *supra* n.41; Andrew Kolodny, *Opioids for Chronic Pain: Addiction is NOT Rare*, YouTube (Oct. 30, 2011), https://www.youtube.com/watch?v=DgyuBWN9D4w&feature=youtu.be.

[49] Jacobs, *One-paragraph letter*, *supra* n.41.

160. In the years following publication of the 1980 Letter to the Editor and the Portenoy Publication, the Manufacturing Defendants introduced powerful prescription opioids into the market. Purdue introduced MS Contin in 1987 and OxyContin in 1995, Janssen introduced Duragesic in 1990, and Cephalon's Actiq was first approved by the FDA in 1998. More recently, Endo's Opana and Opana ER were approved by the FDA in 2006, as were Janssen's Nucynta in 2008 and Nucynta ER in 2011, Cephalon's Fentora in 2006 and Insys' Subsys in 2012.

161. These branded prescription opioids and their generic counterparts are highly addictive. Between doses, patients can suffer body aches, nausea, sweats, racing heart, hypertension, insomnia, anxiety, agitation, opioid cravings, opioid-induced hyperalgesia (heightened sensitivity to pain) and other symptoms of withdrawal. When the agony is relieved by the next dose, it creates a cycle of dysphoria and euphoria that fosters addiction and dependence.

162. Despite prescription opioids' highly addictive qualities, the Manufacturing Defendants launched aggressive pro-opioid marketing efforts that caused a dramatic shift in the public's and prescribers' perception of the safety and efficacy of opioids for chronic long-term pain and everyday use. Contrary to what doctors had previously understood about opioid risks and benefits, they were encouraged for the last two decades by the Manufacturing Defendants to prescribe opioids aggressively, and were assured, based on false evidence provided directly by the Manufacturing Defendants and numerous medical entities funded by the Manufacturing Defendants and others with financial interests in generating more opioid prescriptions, that: (a) the risk of becoming addicted to prescription opioids among patients being treated for pain was

low, even under 1%; and (b) great harm was caused by "undertreated pain." These two foundational falsehoods led directly to the current opioid crisis.

163. The Defendants' strategy was a striking marketing success. It was designed to redefine back pain, neck pain, headaches, arthritis, fibromyalgia and other common conditions suffered by most of the population at some point in their lives as a single malady – chronic pain – that doctors and patients should take seriously and for which opioids were an appropriate, successful and low-risk treatment. Indeed, studies now show more than 85% of patients taking OxyContin at common doses are doing so for chronic non-cancer pain.[50]

164. This false and misleading marketing strategy continued despite studies revealing that up to 56% of patients receiving long-term prescription opioid painkillers for chronic back pain progress to addictive opioid use, including patients with no prior history of addiction.[51]

165. Thus, based on false and incomplete evidence, the Manufacturing Defendants expanded their market exponentially from patients with end-stage cancer and acute pain, an obviously limited customer base, to anyone suffering from chronic pain, which by some accounts includes approximately 100 million Americans – nearly one-third of the country's population.[52] The treatment of chronic pain includes patients whose general health is good enough to refill prescriptions month after month, year after year, and the promotion, distribution (without reporting suspicious sales) and rampant sale of opioids for such treatment has made Defendants

[50] Ryan, *OxyContin goes global*, *supra* n.13.
[51] Lembke (2016), *supra* n.17, at 22 (citing Martell, *Systematic Review*, *supra* n.18); see also Krebs, *Effect of Opioid vs. Nonopioid Medications*, *supra* n.21 (describing JAMA study that concluded opioids were not superior to non-steroidal anti-inflammatory drugs ("NSAIDs") like ibuprofen to treat long-term pain).
[52] *AAPM Facts and Figures on Pain*, The American Academy of Pain Medicine, https://painmed.org/about/position-statements/use-of-opioids-for-the-treatment-of-chronic-pain (last visited Sept. 19, 2019).

billions of dollars. It has also led to the prevalence of opioid addiction and the overdose crisis in nationwide.

2. The Fraudulent Sales Practices.

166. As set forth below, the Manufacturing Defendants employed a variety of strategies to normalize the use of opioids for chronic long-term pain without informing the public and prescribers about the very significant risks of addiction, overdose and death.

3. The Manufacturing Defendants And Unnamed Co-Conspirators[53] Funded Front Organizations that Published and Disseminated False and Misleading Marketing Materials.

167. The Manufacturing Defendants sponsored purportedly neutral medical boards and foundations that educated doctors and set guidelines for the use of opioids in medical treatment in order to promote the liberal prescribing of opioids for chronic pain. The following organizations, funded by the Manufacturing Defendants, advised doctors that liberal prescribing of opioids was both safe and effective. In truth, it was neither.

168. **Federation of State Medical Boards**: The Federation of State Medical Boards ("FSMB") is a national organization that functions as a trade group representing the 70 medical and osteopathic boards in the United States. The FSMB often develops guidelines that serve as the basis for model policies with the stated goal of improving medical practice. The Sacklers through Purdue, as well as Defendants Cephalon and Endo have provided substantial funding to the FSMB.

169. In 2007, the FSMB printed and distributed a physician's guide on the use of opioids to treat chronic pain titled, "Responsible Opioid Prescribing" by Dr. Scott M. Fishman ("Fishman"). After the guide (in the form of a book, still available for sale on Amazon) was

[53] Purdue and Mallinckrodt, both highly culpable manufacturers of opioids, have both filed for Bankruptcy and are therefore not named as defendants at this time.

adopted as a model policy, the FSMB reportedly asked Purdue for $100,000 to help pay for printing and distribution. Ultimately, the guide was disseminated by the FSMB to 700,000 practicing doctors.

170. The guide's clear purpose is to focus prescribers on the purported under-treatment of pain and falsely assure them that opioid therapy is an appropriate treatment for chronic, non-cancer pain. It contains lies such as, *"Opioid therapy to relieve pain and improve function is a legitimate medical practice for* acute and *chronic pain of* both cancer and *non-cancer origins*."[54]

171. While it acknowledges the risk of "abuse and diversion" (with little attention to addiction), the guide purports to offer "professional guidelines" that will "easily and efficiently" allow physicians to manage that risk and "minimize the potential for [such] abuse."[55]

172. The guide further warns physicians to "[b]e aware of the distinction between pseudoaddiction and addiction" and teaches that behaviors such as "[r]equesting [drugs] by name," "[d]emanding or manipulative behavior," "[o]btaining opioid drugs from more than one physician" and "[h]oarding opioids," which are, in fact, signs of genuine addiction, are all really just signs of "pseudoaddiction."[56] It defines "Physical Dependence" as an acceptable result of opioid therapy not to be equated with addiction, and it states that while "[i]t may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications," there could be other acceptable reasons for non-adherence.[57] The guide, sponsored by the Manufacturing Defendants and their pain foundations, became the seminal authority on opioid prescribing for the medical profession

[54] Scott M. Fishman, *Responsible Opioid Prescribing: A Physician's Guide* 8-9 (Waterford Life Sciences 2007).
[55] *Id.* at 9.
[56] *Id*. at 62.
[57] *Id*.

and dramatically overstated the safety and efficacy of opioids and understated the risk of opioid addiction.

173. In 2012, Fishman updated the guide and continued emphasizing the "catastrophic" "under-treatment" of pain and the "crisis" such under-treatment created:

> Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, *it's critical to remember that the problem of unrelieved pain remains as urgent as ever*.[58]

174. In another guide by Fishman, he continues to downplay the risk of addiction: "I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a 'chemical coper' and an addict."[59] The guide also continues to present symptoms of addiction as symptoms of "pseudoaddiction."

175. The heightened focus on the under-treatment of pain was a concept designed by Defendants to sell opioids. *The FSMB actually issued a report calling on medical boards to punish doctors for inadequately treating pain*.[60] Among the drafters of this policy was Dr. J. David Haddox ("Haddox"), who coined the term "pseudoaddiction," a term which wholly lacked any scientific basis but quickly became a common way for the Manufacturing Defendants and their allies to promote the use of opioids even to patients displaying addiction symptoms. Haddox later became a Purdue vice president who likened OxyContin to a vegetable, stating at a 2003 conference at Columbia University,[61] "If I gave you a stalk of celery and you ate that, it

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[58] Scott M. Fishman, *Responsible Opioid Prescribing: A Clinician's Guide* 10-11 (Waterford Life Sciences 2012).
[59] Scott M. Fishman, Listening to Pain: A Physician's Guide to Improving Pain Management Through Better Communication 45 (Oxford Univ. Press 2012).
[60] Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, at A1.
[61] Gounder, *Who Is Responsible*, *supra* n.47.

would be healthy. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[62]

176. As noted in ¶¶ 222-231 *infra*, in 2012 and again in 2017, the guides and the sources of their funding became the subject of a Senate investigation.

177. On June 8, 2012, the FSMB submitted a letter to the Senate Finance Committee concerning its investigation into the abuse and misuse of opioids.[63] While the letter acknowledged the escalation of both drug abuse and deaths resulting from prescription painkillers, the FSMB continued to focus on the "serious and related problem" that "[m]illions of Americans suffer from debilitating pain – a condition that, for some, can be relieved through the use of opioids." Among other things, the letter stated that "[s]tudies have concluded that both acute pain and chronic pain are often under-treated in the United States, creating serious repercussions that include the loss of productivity and quality of life." The letter cited no such studies. The letter also confirmed that the FSMB's "Responsible Opioid Prescribing: A Physician's Guide" had been distributed in all 50 states and the District of Columbia.

178. In addition, the FSMB letter disclosed payments the FSMB had received from organizations that develop, manufacture, produce, market or promote the use of opioid-based drugs from 1997 through the present. Included in the payments received are the following payments from the Sacklers through Purdue, and from other Defendants:

Company	***Fiscal Year***	***Amount***
Purdue	2001	$38,324.56
	2002	$10,000.00
	2003	$85,180.50
	2004	$87,895.00

[62] Keefe, *Empire of Pain, supra* n.27.
[63] June 8, 2012 Letter from Federation of State Medical Boards to U.S. Senators Max Baucus and Charles Grassley, https://assets.documentcloud.org/documents/3109089/FSMB-Response-Letter-to-US-Senate.pdf.

	2005	$244,000.00
	2006	$207,000.00
	2007	$50,000.00
	2008	$100,000.00
	Total Purdue Payments	***$822,400.06***
Endo	2007	$40,000.00
	2008	$100,000.00
	2009	$100,000.00
	2011	$125,000.00
	2012	$46,620.00
	Endo Payments	***$411,620.00***
Cephalon	2007	$30,000.00
	2008	$100,000.00
	2011	$50,000.00
	Total Cephalon Payments	***$180,000.00***
Mallinckrodt	2011	$100,000.00
	Total Mallinckrodt Payments	***$100,000.00***

179. The letter also disclosed payments of $40,000 by Endo and $50,000 by Purdue to directly fund the production of "Responsible Opioid Prescribing" and revealed that sales of "Responsible Opioid Prescribing" had generated more than $2.75 million in revenues in California alone.[64]

180. **The Joint Commission**: The Joint Commission is an organization that establishes standards for treatment and accredits healthcare organizations in the United States. The Manufacturing Defendants, including the Sacklers through Purdue, contributed misleading and groundless teaching materials and videos to the Joint Commission, which emphasized what Big Pharma coined the "under-treatment of pain," referenced pain as the "fifth vital sign" (the first and only unmeasurable/subjective "vital sign") that must be monitored and treated, and encouraged the use of prescription opioids for chronic pain while minimizing the dangers of addiction. It also called doctors' concerns about addiction "inaccurate and exaggerated."

181. In 2000, the Joint Commission printed a book for purchase by doctors as part of required continuing education seminars that cited studies, claiming "*there is no evidence that*

[64] *Id*. at 15.

addiction is a significant issue when persons are given opioids for pain control." The book was sponsored by Purdue.

182. In 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies[65]) collaborated to issue a 101-page monograph titled, "Pain: Current understanding of assessment, management, and treatments." The monograph states falsely that beliefs about opioids being addictive are "erroneous."[66]

183. The Manufacturing Defendants' infiltration and influence over the Joint Commission's standards and literature exerted overwhelming pressure on doctors to treat and eliminate pain. As more and more doctors migrated from private practice to integrated healthcare systems in the 2000s, treatment options were dictated by, among other things, the Joint Commission's guidelines.[67] Consistent with the Joint Commission's guidelines, doctors who left pain untreated were viewed as demonstrating poor clinical skills and/or being morally compromised.[68]

184. The U.S. General Accounting Office's December 2003 Report to Congressional Requesters confirms that Purdue funded the "pain management educational courses" that taught the new standard of care for treating pain. It further revealed that Purdue disseminated educational materials on pain management, which "'facilitated [Purdue's] access to hospitals to promote OxyContin.'"[69]

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[65] Funded by Johnson & Johnson, Purdue and Teva, among others.
[66] National Pharmaceutical Council, Inc., *Pain: Current Understanding of Assessment, Management, and Treatments* at 16-17 (Dec. 2001), http://www.npcnow.org/system/files/research/download/Pain-Current-Understanding-of-Assessment-Management-and-Treatments.pdf (footnotes and citations omitted).
[67] *Id*. at 119.
[68] *Id*. at 42.
[69] Gounder, *Who Is Responsible*, *supra* n.47. U.S. General Accounting Office,

185. **The American Pain Foundation**: The American Pain Foundation ("APF"), described itself as the nation's largest organization for pain patients.[70] While APF held itself out as an independent patient advocacy organization, in reality it received 90% of its funding in 2010 from the drug and medical-device industry, including from the Sackler Family (through Purdue), and defendants Endo, Janssen and Cephalon. It received more than $10 million in funding from opioid manufacturers from 2007 to 2012, when it shut down days after the U.S. Senate Committee on Finance ("Senate Finance Committee") launched an investigation of the APF's promotion of prescription opioids.

186. The APF's guides for patients, journalists, and policymakers trivialized the risk of addiction and greatly exaggerated the benefits associated with opioid painkillers.[71]

187. For example, in 2001, the APF published "Treatment Options: A Guide for People Living with Pain."[72] The guide, which was produced with support from companies including Cephalon and Purdue, misrepresented the risks associated with opioid use. Among other things, the guide:

- lamented that opioids were sometimes called narcotics because "*[c]alling opioid analgesics 'narcotics' reinforces myths and misunderstandings* as it places emphasis on their potential abuse rather than on the importance of their use as pain medicines";[73]

GAO-04-110, *Prescription Drugs, OxyContin Abuse and Diversion and Efforts to Address the Problem* (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.

[70] The APF was the focus of a December investigation by ProPublica in the *Washington Post* that detailed its close ties to drugmakers.

[71] Charles Ornstein & Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57 PM), https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups/ (hereinafter, "Ornstein, *American Pain Foundation*").

[72] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Dec. 14, 2019).

[73] *Id*. at 11.

- stated that "[o]pioids are an essential option for treating *moderate* to severe pain associated with surgery or trauma";[74] and
- opined that "[r]estricting access to the most effective medications for treating pain [opioids] is not the solution to drug abuse or addiction."[75]

The guide included blurbs from Portenoy, who is quoted as saying "[t]his is a very good resource for the pain patient," and Fishman, who is quoted as saying, "[w]hat a great job! Finally, a pill consumer resource created for patients with pain. A 'must have' for every physician's waiting room."[76]

188. In 2009, Endo sponsored the APF's publication and distribution of "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families" ("Exit Wounds"). Among other false statements, Exit Wounds reported: "Long experience with opioids shows that *people who are not predisposed to addiction are very unlikely to become addicted to opioid pain medications*."[77] Endo, through the APF, thus distributed false information with the purpose of providing veterans false information they could use to self-advocate for opioids while omitting a discussion of the risks associated with opioid use.

189. In 2009, the APF played a central role in a first-of-its-kind, web-based series called, "Let's Talk Pain," hosted by veteran TV journalist Carol Martin. The series brought together healthcare providers and "people with pain to discuss a host of issues from managing health care for pain to exploring integrative treatment approaches to addressing the psychological aspects associated with pain." The "Let's Talk Pain" talk show is still available online. In the very first episode of this talk show, the following exchange took place:

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[74] *Id*.
[75] *Id*. at 15.
[76] *Id.* at 76.
[77] Derek McGinnis, Exit Wounds: A Survival Guide to Pain Management for Returning Veterans and Their Families, American Pain Foundation (2009), 107.

> [**Teresa Shaffer (APF Action Network Leader)**:] As a person who has been living with pain for over 20 years, opioids are a big part of my pain treatment. And I have been hearing such negative things about opioids and the risk factors of opioids. Could you talk with me a little bit about that?
>
> [**Dr. Al Anderson (AAPM Board of Directors)**:] The general belief system in the public is that the opioids are a bad thing to be giving a patient. Unfortunately, it's also prevalent in the medical profession, so patients have difficulty finding a doctor *when they are suffering from pain for a long period of time*, especially *moderate* to severe pain. And *that's the patients that we really need to use the opioids* methods of treatment, because they are the ones who need to have some help with the function and they're the ones that need to have their pain controlled enough so that they can increase their quality of life.[78]

190. In reality, there is little scientific evidence to support the contention that opioids taken long-term improve function or quality of life for chronic pain patients.[79] To the contrary, there is ample evidence that opioids impose significant risks and adverse outcomes on long-term users and that they may actually reduce function.[80] As a recent article in the *New England Journal of Medicine* concluded: "Although opioid analgesics rapidly relieve many types of acute pain and improve function, the benefits of opioids when prescribed for chronic pain are much more questionable." The article continues, "opioid analgesics are widely diverted and improperly used, and the widespread use of the drugs has resulted in a national epidemic of opioid overdose

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[78] *Episode 1: Safe Use of Opioids (PainSAFE)*, Let's Talk Pain (Sept. 28, 2010), https://www.youtube.com/watch?v=zeAlVAMRgsk.

[79] Lembke (2016), supra n.17 at 59.

[80] Discussing the CDC's "March 2016 Guidelines for Prescribing Opioids for Chronic Pain," doctors wrote:

> Most placebo-controlled, randomized trials of opioids have lasted 6 weeks or less, and we are aware of no study that has compared opioid therapy with other treatments in terms of long-term (more than 1 year) outcomes related to pain, function, or qualify of life. The few randomized trials to evaluate opioid efficacy for longer than 6 weeks had consistently poor results. In fact, several studies have showed that use of opioids for chronic pain may actually worsen pain and functioning, possibly by potentiating pain perception.

Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guidelines*, 374 New Eng. J. Med. 1501-04 (Apr. 21, 2016), https://www.nejm.org/doi/full/10.1056/NEJMp1515917.

deaths and addictions."[81] More recently still, a study published in *JAMA* concluded that "[t]reatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months."[82]

191. The APF also developed the National Initiative on Pain Control ("NIPC"), which ran a facially unaffiliated website, www.painknowledge.org. NIPC promoted itself as an education initiative and promoted its expert leadership team, including purported experts in the pain management field. The website painknowledge.org promised that, on opioids "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life as a benefit of opioid therapy. In a brochure available on painknowledge.org titled, "Pain: Opioid Facts," the NIPC misleadingly stated that "people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted" and even refused to rule out the use of opioid pain relievers for patients who have a history of addiction to opioids.[83]

192. In or around 2011, the APF published the "Policymaker's Guide," sponsored by Purdue, which dispelled the notion that "strong pain medication leads to addiction" by characterizing it as a "*common misconception*[]":

> *Many people living with pain, and even some health care practitioners, falsely believe that opioid pain medicines are universally addictive.* As with any medication, there are risks, but these risks can be managed when these medicines

[81] Nora D. Volkow & A. Thomas McLellan, Opioid Abuse in Chronic Pain – Misconceptions and Mitigation Strategies, 374 New Eng. J. Med. 1253-63 (Mar. 31, 2016).
[82] Krebs, *Effect of Opioid vs. Nonopioid Medications*, supra n.21.
[83] *Pain: Opioid Facts*, Pain Knowledge (2007) https://web.archive.org/web/20101007102042/http://painknowledge.org/patiented/pdf/Patient%20Education%20b380_b385%20%20pf%20opiod.pdf (last visited Oct. 1, 2019).

> are properly prescribed and taken as directed. For more information about safety issues related to opioids and other pain therapies, visit http://www.painsafe.org.[84]

193. The guide further falsely asserts that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients.[85]

194. In December 2011, the *Washington Post* reported on ProPublica's investigation of the APF, which detailed the APF's close ties to drugmakers:

> *The foundation collected nearly 90 percent of its $5 million in funding last year from the drug and medical-device industry – and closely mirrors its positions*, an examination by ProPublica found.[86]

195. **American Academy of Pain Medicine (AAPM) and American Pain Society (APS)**: The Manufacturing Defendants—including at least Endo, Janssen and the Sackler Family through Purdue—have contributed funding to the AAPM and the APS for decades.

196. In 1997, the AAPM issued a "consensus" statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. At the time, the chairman of the committee that issued the statement, Dr. J. David Haddox, was a

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[84] *A Policymaker's Guide to Understanding Pain & Its Management*, American Pain Foundation at 5 (Oct. 2011), https://assets.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.

[85] The "Policymaker's Guide" cites for support "Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects," a review published in 2006 in the *Canadian Medical Association Journal*. *Id*. at 34. However, the review concludes: "For functional outcomes, *the other analgesics were significantly more effective than were opioids*." Andrea D. Furlan et al., *Opioids for chronic noncancer pain: a meta-analysis of effectiveness and side effects*, 174(11) Canadian Med. Assoc. J. 1589-94 (May 23, 2006), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1459894/. The Purdue-sponsored guide failed to disclose both this conclusion and the fact that the review analyzed studies that lasted, on average, five weeks and therefore could not support the long-term use of opioids.

[86] Charles Ornstein & Tracy Weber, *Patient advocacy group funded by success of painkiller drugs, probe finds*, Wash. Post (Dec. 23, 2011), https://www.washingtonpost.com/national/health-science/patient-advocacy-group-funded-by-successof-painkiller-drugs-probe-finds/2011/12/20/gIQAgvczDP_story.html?utm_term=.22049984c606.

paid speaker for Purdue. Haddox was later hired as Purdue's vice president for health policy. The consensus statement, which also formed the foundation of the AAPM's1998 guidelines, was published on the AAPM's website. AAPM's corporate council includes Purdue, Depomed, Inc. ("Depomed"), Teva and other pharmaceutical companies. AAPM's past presidents include Haddox (1998), Fishman (2005), Dr. Perry G. Fine ("Fine") (2011) and Lynn R. Webster ("Webster") (2013), all of whose connections to the opioid manufacturers are well documented.

197. At or about the same time, the APS introduced the "pain as the 5th vital sign" campaign, followed soon thereafter by the U.S. Department of Veterans Affairs incorporating that message as part of its national pain management strategy.

198. The AAPM and APS issued guidelines in 2009 ("2009 Guidelines") that continued to recommend the use of opioids to treat chronic pain. Fourteen of the twenty-one panel members who drafted the 2009 Guidelines received funding from Janssen, Cephalon, Endo or Purdue.

199. The 2009 Guidelines falsely promoted opioids as safe and effective for treating chronic pain and concluded that the risk of addiction was manageable for patients regardless of past abuse histories.[87] The 2009 Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; they were reprinted in the journal *Pain*, have been cited hundreds of times in the academic literature, and remain available online. The Manufacturing Defendants widely cited and promoted the 2009 Guidelines without disclosing the absence of evidence to support their conclusions.

[87] Roger Chou et al., *Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, 10(2) J. Pain 113-30 (Feb. 2009), http://www.jpain.org/article/S1526-5900(08)00831-6/pdf (hereinafter, "Chou, *Clinical Guidelines*").

200. **The Alliance for Patient Access**: Founded in 2006, the Alliance for Patient Access ("APA") is a self-described patient advocacy and health professional organization, which styles itself as "a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care."[88] It is run by Woodberry Associates LLC, a lobbying firm also established in 2006.[89] As of June 2017, the APA listed 30 "Associate Members and Financial Supporters." The list included Johnson & Johnson, Endo, Mallinckrodt, Purdue, Cephalon, and Allergan.

201. APA's board members have also directly received substantial funding from pharmaceutical companies.[90] For instance, board vice president Dr. Srinivas Nalamachu ("Nalamachu"), who practices in Kansas, received more than $800,000 from 2013 through 2015 from pharmaceutical companies – nearly all of it from manufacturers of opioids or drugs that treat opioids' side-effects, including from Endo, Insys, Purdue and Cephalon. Nalamachu's clinic was raided by Federal Bureau of Investigation ("FBI") agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys.[91] Other past and present board members have included Dr. Robert A. Yapundich from North Carolina, who received $215,000 from 2013 through 2015 from pharmaceutical companies, including payments

[88] *About AfPA*, The Alliance for Patient Access, http:// allianceforpatientaccess.org (last visited Dec. 14, 2018). References herein to APA include two affiliated groups: The Global Alliance for Patient Access and the Institute for Patient Access.

[89] Mary Chris Jaklevic, *Non-profit Alliance for Patient Access uses journalists and politicians to push Big Pharma's agenda*, Health News Review (Oct. 2, 2017), https://www.healthnewsreview.org/2017/10/non-profit-alliance-patient-access-uses-journalists-politicians-push-big-pharmas-agenda/ (hereinafter, "Jaklevic, *Non-profit Alliance for Patient Access*").

[90] All information concerning pharmaceutical company payments to doctors in this paragraph is from ProPublica's Dollars for Docs database, available at https://projects.propublica.org/docdollars/.

[91] Andy Marso, *FBI seizes records of Overland Park pain doctor tied to Insys*, Kansas City Star (July 20, 2017), https://www.kansascity.com/news/business/health-care/article162569383.html.

by Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than $240,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Mallinckrodt and Cephalon; Dr. Howard Hoffberg from Maryland, who received $153,000 between 2013 and 2015 from pharmaceutical companies, including Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received $700,000 between 2013 and 2015 from pharmaceutical companies.

202. Among its activities, the APA issued a white paper titled, "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse."[92] Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user friendly, unfair to physicians, and of questionable efficacy.[93]

203. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

> Although well intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations, must have a Board certified medical director, may need to pay for annual inspections, and are subject to increased record keeping and reporting requirements. . . .
>
> [I]t is not even certain that the regulations are helping prevent abuses.[94]

204. In addition, in an echo of earlier industry efforts to push back against what they termed "opiophobia," the white paper laments the stigma associated with prescribing and taking pain medication:

> Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can't get their prescriptions for pain

[92] *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Institute for Patient Access (Oct. 2013), https://1yh21u3cjptv3xjder1dco9mx5s-wpengine.netdna-ssl.com/wp-content/uploads/2013/12/PT_White-Paper_Finala.pdf.
[93] *Id*. at 4-5 (footnote omitted).
[94] *Id*. at 5-6

> medication filled at a pharmacy, they may feel like they are doing something wrong – or even criminal. . . . Physicians can face similar stigma from peers.[95]

205. In conclusion, the white paper states that "[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs."[96]

206. ***Exposing the Financial Ties Between Opioid Manufacturers and Third-Party Groups***: A February 12, 2018 report titled, "Fueling an Epidemic Report Two: Exposing the Financial Ties Between Opioid Manufacturers and Third Party Advocacy Groups" and issued by the U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member Claire McCaskill's Office, sheds additional light on the financial connections between opioid manufacturers and purportedly neutral patient advocacy organizations and medical professional societies that, unsurprisingly, have "echoed and amplified messages favorable to increased opioid use – and ultimately the financial interests of opioid manufacturers."[97]

207. According to the report, the five manufacturers whose information was subpoenaed by Senator McCaskill alone contributed almost $9 million combined to patient advocacy organizations and professional societies operating in the opioids policy area:

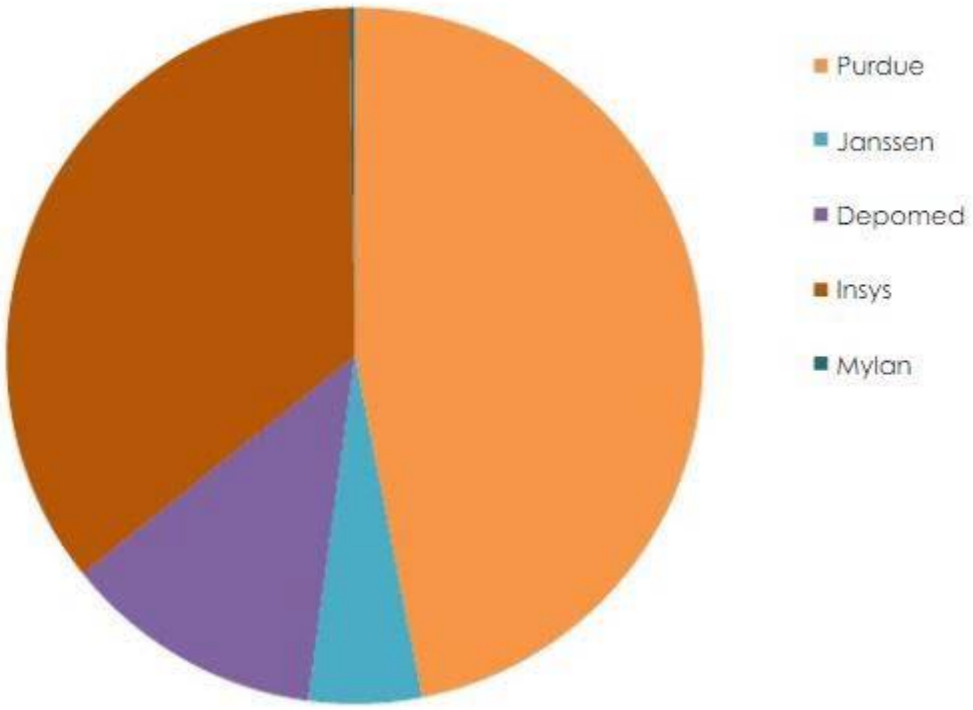
[95] *Id*. at 6.
[96] *Id*. at 7.
[97] *February 2018 McCaskill Report, supra* n.15.

FIGURE 1: Manufacturer Payments to Selected Groups, 2012-2017

	Purdue[22]	Janssen[23]	Depomed	Insys	Mylan	Total
Academy of Integrative Pain Management	$1,091,024.86	$128,000.00	$43,491.95	$3,050.00[24]	$0.00	$1,265,566.81
American Academy of Pain Medicine	$725,584.95	$83,975.00	$332,100.00	$57,750.00	$0.00	$1,199,409.95
AAPM Foundation	$0.00	$0.00	$304,605.00	$0.00	$0.00	$304,605.00
ACS Cancer Action Network	$168,500.00[25]	$0.00	$0.00	$0.00	$0.00	$168,500.00
American Chronic Pain Association	$312,470.00	$50,000.00	$54,670.00	$0.00	$0.00	$417,140.00
American Geriatrics Society	$11,785.00[26]	$0.00	$0.00	$0.00	$0.00	$11,785.00
American Pain Foundation	$25,000.00	$0.00	$0.00	$0.00	$0.00	$25,000.00
American Pain Society	$542,259.52	$88,500.00	$288,750.00	$22,965.00	$20,250.00	$962,724.52
American Society of Pain Educators	$30,000.00	$0.00	$0.00	$0.00	$0.00	$30,000.00
American Society of Pain Management Nursing	$242,535.00	$55,177.85[27]	$25,500.00[28]	$0.00	$0.00	$323,212.85
The Center for Practical Bioethics	$145,095.00	$18,000.00	$0.00	$0.00	$0.00	$163,095.00
The National Pain Foundation[29]	$0.00	$0.00	$0.00	$562,500.00	$0.00	$562,500.00
U.S. Pain Foundation	$359,300.00	$41,500.00	$22,000.00	$2,500,000.00[30]	$0.00	$2,922,800.00
Washington Legal Foundation	$500,000.00	$0.00	$0.00	$0.00	$0.00	$500,000.00
	$4,153,554.33	$465,152.85	$1,071,116.95	$3,146,265.00	$20,250.00	$8,856,339.13

208. As shown below, payments from Purdue comprise roughly half this funding, with Insys providing the second-largest amount:

FIGURE 2: Percentages of Total Payments by Manufacturer, 2012-2017



209. While Purdue's payments slowed starting in 2016, Insys' payments increased exponentially in 2017:

FIGURE 3: Manufacturer Yearly Payment Totals, 2012-2017

	2012	2013	2014	2015	2016	2017	Total
Purdue	$824,227.86	$973,328.00	$812,451.95	$935,344.00	$558,067.52	$50,135.00	$4,153,554.33
Janssen	$239,902.85[36]	$99,250.00	$126,000.00				$465,152.85
Depomed	$73,080.00	$135,300.00	$113,600.00	$350,000.00	$318,257.47	$80,879.48	$1,071,116.95
Insys	$14,040.00	$68,000.00	$34,200.00	$530,025.00		$2,500,000.00	$3,146,265.00
Mylan				$15,000.00	$2,500.00	$2,750.00	$20,250.00
Total	$1,151,250.71	$1,275,878.00	$1,086,251.95	$1,830,369.00	$878,824.99	$2,633,764.48	$8,856,339.13

210. In addition to the nearly $9 million in payments to purportedly neutral patient advocacy organizations and medical professional societies, the five subpoenaed opioid manufacturers made an additional $1.6 million in payments to the organizations' and societies' group executives, staff members, board members, and advisory board members. When payments

from all opioid manufacturers are tabulated, more than $10.6 million was paid to individuals affiliated with such organizations and societies from 2013 through the date of the report:

FIGURE 8: Payments from All Opioid Manufacturers to Group-Affiliated Individuals, 2013-Present[52]

	Manufacturer Payments to Affiliated Individuals
The National Pain Foundation	$8,307,243.47
AAPM Foundation	$798,051.22
American Society of Pain Educators	$749,564.78
American Academy of Pain Medicine	$204,631.53
American Pain Society	$187,699.34
ACS Cancer Action Network	$154,578.09
American Chronic Pain Association	$145,861.30
Academy of Integrative Pain Management	$82,596.98
The Center for Practical Bioethics	$16,945.88
American Geriatrics Society	$7,548.35
U.S. Pain Foundation	$138.91
American Pain Foundation	N/A
American Society of Pain Management Nursing	N/A
Washington Legal Foundation	N/A
Total	$10,654,859.85

211. Included in the above-listed payments were payments of more than $140,000 from opioid manufacturers, including Endo, Purdue, and Mallinckrodt to ten members of the American Chronic Pain Association Advisory Board; $170,000 from Insys to National Pain Foundation ("NPF") chairman and founder D. Daniel Bennett; and more than $950,000 to members of the NPF board of directors from various opioid manufacturers, including more than $250,000 from Insys alone.

212. Worse still, the organizations provided limited disclosures of these sources of funding – when they provided any information at all. The American Society of Pain Educators, the NPF, and the Academy of Integrative Pain Management provided no information concerning

their policies for disclosing donors or donations, while several others stated explicitly that they did not disclose any information concerning donor relationships. When the groups investigated did disclose their sources of funding, they did so without providing specifics such as donation amounts.

213. Most importantly, many of the groups investigated "amplified or issued messages that reinforce industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of addiction and promoting opioids for chronic pain." Several of the groups "also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for overprescription and misbranding."[98] The report provided details regarding four ways the groups investigated set about these tasks.

214. First, the report states that "[m]any of the groups have issued guidelines to physicians and other health practitioners that minimize the risk of opioid addiction or emphasize the long-term use of opioids to treat chronic pain."[99] The report provides examples, including the AAPM's and APS's 1997 consensus statement endorsing opioids for chronic pain and stating that the risk of addiction was low, and the 2009 guidelines by the AAPM and the APS allegedly promoting opioids as safe and effective for chronic pain and concluding the risk of addiction was manageable regardless of past abuse history.

215. In conclusion, the report found that, while health advocacy organizations are "among the most influential and trusted stakeholders in U.S. health policy," the reality is that their "positions closely correspond to the marketing aims of pharmaceutical and device companies," including in the area of opioids policy. "The findings in this report indicate that this

[98] *Id*. at 12.
[99] *Id*.

tension exists in the area of opioids policy – that organizations receiving substantial funding from manufacturers have, in fact, amplified and reinforced messages favoring increased opioid use." This amplification "may have played a significant role in creating the necessary conditions for the U.S. opioids epidemic."[100]

4. The Manufacturing Defendants Paid Key Opinion Leaders and Sponsored Speakers' Bureaus to Disseminate False and Misleading Messaging.

216. The Manufacturing Defendants have paid millions of dollars to physicians to promote aggressive prescribing of opioids for chronic pain. Recently released federal data show that the Manufacturing Defendants increased such payments to physicians who treat chronic pain even while the opioid crisis accelerated and overdose deaths from prescription opioids and related illicit drugs, such as heroin, soared to record rates.[101] These payments come in the form of consulting and speaking fees, free food and beverages, discount coupons for drugs, and other freebies. The total payments from the Manufacturing Defendants to doctors related to opioids doubled from 2014 to 2015. Moreover, according to experts, research shows even small amounts of money can have large effects on doctors' prescribing practices.[102] Physicians who are high prescribers are more likely to be invited to participate in Defendants' speakers' bureaus. According to a study published by the U.S. National Institutes of Health, "[s]peakers' bureau activities fall squarely within this definition of peer selling and hence product endorsement."[103]

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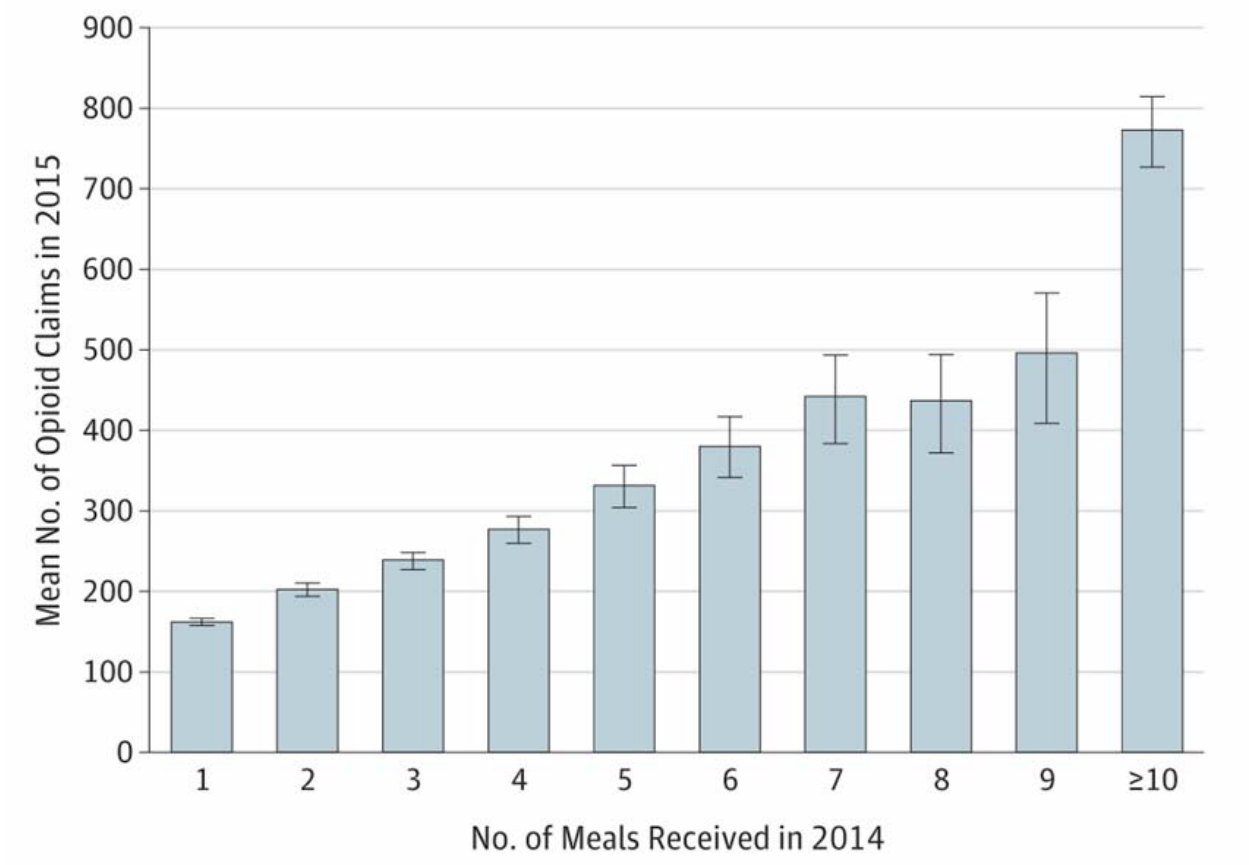
[100] *Id*. at 17.
[101] Joe Lawlor, *Even amid crisis, opioid makers plied doctors with perks*, Portland Press Herald (Dec. 25, 2016), http://www.pressherald.com/2016/12/25/even-amid-crisis-opioid-makers-plied-doctors-with-perks/.
[102] *Id*.
[103] Lynette Reid & Matthew Herder, *The speakers' bureau system: a form of peer selling*, 7(2) Open Med. e31-e39 (Apr. 2, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863750/.

217. According to a research letter published in *JAMA Internal Medicine* on May 14, 2018, doctors' mean number of opioids prescriptions increased with the number of free meals they received from an opioid company.[104] The study found that Insys accounted for 50% of the non-research payments.[105]



218. The use of speakers' bureaus has led to substantial ethical concerns within the medical field. A 2013 publication by the Institute on Medicine as a Profession summarized that

[104] Scott E. Hadland et al., *Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing*, JAMA Intern. Med. (May 14, 2018), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2681059. The study looked at the Open Payments database, which was used to pull out non-research payments to doctors in 2014. It then compared that data to claims in the Medicare Part D Opioid Prescriber Summary File from doctors who wrote opioid prescriptions in 2015, leaving in "all physicians with complete, nonduplicate information who had at least 10 opioid claims during 2015."

[105] *Id.*

the bureaus "leverage the credibility of physicians in order to promote the use of pharmaceutical products" and "Exposure to industry-sponsored speaking events is associated with decreased quality of prescribing."[106]

219. For example, Fishman is a physician whose ties to the opioid drug industry are legion. He has served as an APF board member and as president of the AAPM and has participated yearly in numerous CME activities for which he received "market rate honoraria." As discussed above, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturing Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter in *JAMA* titled, "Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion."[107]

220. Similarly, Fine's ties to the Manufacturing Defendants have been well documented.[108] He has authored articles and testified in court cases and before state and federal committees, and he, too, has served as president of the AAPM and argued against legislation restricting high-dose opioid prescription for non-cancer patients. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500

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[106] *Speakers' Bureaus: Best Practices for Academic Medical Centers*, IMAP (Oct. 10, 2013), http://imapny.org/wp-content/themes/imapny/File%20Library/Best%20Practice%20toolkits/Best-Practices_Speakers--bureaus.pdf (citing research in *JAMA, The Journal of Law, Medicine & Ethics* and *Academic Psychiatry*).

[107] Scott M. Fishman, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*, 306(13), JAMA 1445 (2011), https://jamanetwork.com/journals/jama/article-abstract/1104464.

[108] Tracy Weber & Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica (Dec. 23, 2011, 2:14 PM), https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry (hereinafter, "Weber, *Two Leaders in Pain*").

pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death.[109] He has also acknowledged having failed to disclose numerous conflicts of interest.

221. Fishman and Fine are only two of the many physicians whom the Manufacturing Defendants paid to promote false or biased information on the use of opioids for chronic pain.

5. Senate Investigations of the Manufacturing Defendants.

222. In May 2012, the Chair and Ranking Member of the Senate Finance Committee, Max Baucus (D-MT) and Chuck E. Grassley (R-IA), launched an investigation into makers of narcotic painkillers and groups that champion them. The investigation was triggered by "an epidemic of accidental deaths and addiction resulting from the increased sale and use of powerful narcotic painkillers," including popular brand names like OxyContin, Vicodin, and Opana.

223. The Senate Finance Committee sent letters to Purdue, Endo, and Johnson & Johnson, as well as five groups that support pain patients, physicians, or research, including the APF, AAPM, APS, University of Wisconsin Pain & Policy Studies Group, and the Center for Practical Bioethics. Letters also went to the FSMB and the Joint Commission. The letters addressed the magnitude of the epidemic and asserted that mounting evidence supports that the pharmaceutical companies may be responsible.[110]

224. The Senators demanded substantial discovery, including payment information from the companies to various groups, including the front organizations identified above, and to

[109] Linda Deutsch, *Doctor: 1,500 pills don't prove Smith was addicted*, Seattle Times (Sept. 22, 2010, 5:16 PM), https://www.seattletimes.com/entertainment/doctor-1500-pills-dont-prove-smith-was-addicted/.

[110] May 8, 2012 Letter from U.S. Senators Charles E. Grassley and Max Baucus to Catherine Underwood, Executive Director, American Pain Society, https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Society.pdf

physicians, including Portenoy, Fishman, and Fine, among others. They asked about any influence the companies had on a 2004 pain guide for physicians that was distributed by the FSMB, on the APS' guidelines, and on the APF's Military/Veterans Pain Initiative. Almost immediately upon the launch of the Senate investigation, the APF shut down "due to irreparable economic circumstances." In 2018, the Finance Committee demanded discovery detailing payments from the Manufacturing Defendants to nonprofit front groups, including those described above and the U.S. Pain Foundation,[111] American Academy of Pain Medicine, American Pain Society, and Center for Practical Bioethics, dating back to 1997.[112] The opioid report resulting from this investigation has not been released publicly.[113]

225. On March 29, 2017, it was widely reported[114] that yet another Senate investigation had been launched by Missouri Senator Claire McCaskill, targeting the heads of Purdue, Janssen/Johnson & Johnson, Insys, Mylan, and Depomed.

226. On September 6, 2017, Senator McCaskill's first report, "Fueling an Epidemic: Insys Therapeutics and the Systemic Manipulation of Prior Authorization," was published. The report found that Insys manipulated the prior authorization process by misleading pharmacy benefit managers ("PBMs") in order to increase sales of the Insys-manufactured opioid,

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[111] Letter from Senator Ron Wyden to Nicole Hemmenway, Interim CEO, U.S. Pain Foundation (Dec. 18, 2018), https://www.finance.senate.gov/imo/media/doc/121818%20Senator%20Wyden%20to%20the%20U.S.%20Pain%20Foundation.pdf.

[112] Thomas Sullivan, Senate Finance Committee Reacts to Reports of Opioid Abuse and Conflict of Interests: Letters to Manufacturers and Organizations (May 6, 2018), https://www.policymed.com/2012/05/senate-finance-committee-reacts-to-reports-of-opioid-abuse-and-conflict-of-interests-letters-to-manufactures-and-organizatio.html.

[113] Paul D. Thacker, *Senators Hatch and Wyden: Do your jobs and release the sealed opioids report*, Stat News (June 27, 2016), https://www.statnews.com/2016/06/27/opioid-addiction-orrin-hatch-ron-wyden/; *see also* Ornstein, *American Pain Foundation*, *supra* n.71.

[114] Nadia Kounang, *Senator McCaskill opens investigation into opioid manufacturers*, CNN (Mar. 29, 2017, 11:06 AM), https://www.cnn.com/2017/03/28/health/senate-opioid-manufacturer-investigation/index.html.

Subsys.[115] The PBM prior authorization process requires additional approval before dispensing and paying for certain powerful and expensive drugs, which, in the case of Subsys, included "confirmation that the patient had an active cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate."[116] The report found Insys actively and systematically misled PBMs about the presence of breakthrough cancer pain in potential Subsys patients to improperly circumvent the process, however.[117] On November 28, 2018, the former Vice President of Sales of Insys pled guilty in federal court to his role in a nationwide conspiracy to bribe medical practitioners to unnecessarily prescribe fentanyl-based pain medication and defraud healthcare insurers.

227. On September 12, 2017, Senator McCaskill convened a Roundtable Discussion on Opioid Marketing. During the hearing, Senator McCaskill stated, "Our national opioid epidemic is complex, but one explanation for this crisis is simple, pure greed."

228. Professor Adriane Fugh-Berman ("Fugh-Berman"), Associate Professor at Georgetown University Medical Center and director of a program at Georgetown called Pharmed Out, which conducts research on and educates the public about inappropriate pharmaceutical company marketing, also testified during the hearing.

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[115] *Fueling an Epidemic: Insys Therapeutics and the Systematic Manipulation of Prior Authorization*, U.S. Senate Homeland Security & Government Affairs Committee, Ranking Member's Office at 2 (Sept. 6, 2017), https://www.hsgac.senate.gov/imo/media/doc/REPORT%20-%20Fueling%20an%20Epidemic%20-%20Insys%20Therapeutics%20and%20the%20Systemic%20Manipulation%20of%20Prior%20Authorization.pdf.

[116] *Id*. (quoting Complaint, *Blue Cross of California, Inc., et al. v. Insys Therapeutics, Inc*., (No. 2:17 CV 02286) (D. Ariz. July 12, 2017).

[117] *Id*.

229. Fugh-Berman answered why doctors were able to be convinced by pharmaceutical companies' marketing efforts:

> Why do physicians fall for this? Well, physicians are overworked, overwhelmed, buried in paperwork and they feel unappreciated. Drug reps are cheerful. They're charming. They provide both appreciation and information. Unfortunately, the information they provide is innately unreliable.
>
> Pharmaceutical companies influence healthcare providers' attitudes and their therapeutic choices through financial incentives that include research grants, educational grants, consulting fees, speaking fees, gifts and meals.

230. Fugh-Berman further described the false information provided by pharmaceutical companies and the industry creation of front organizations, including the APF, to pass industry influenced regulations and policies:

> Pharmaceutical companies convinced healthcare providers that they were opiophobic and that they were causing suffering to their patients by denying opioids to patients with back pain or arthritis.

231. In addition, Fugh-Berman pointed out that promotion of opioids remains ongoing despite increasing public concern about their use:

> Promotion of opioids is not in the past. Between 2013 and 2015, one in 12 physicians took out money from opioid manufacturers, a total of more than $46 million. Industry-friendly messages that pharmaceutical companies are currently perpetuating reassure physicians that prescribing opioids is safe as long as patients do not have a history of substance abuse or mental illness.

6. The Devastating Impact of the Manufacturing Defendants' Propaganda Campaign.

232. As stated, the impact of the Manufacturing Defendants' false messaging has been profound. The drug companies profited handsomely as more and more people became addicted to opioids and died of overdoses.[118]

[118] German Lopez, *How big pharma got people hooked on dangerous opioids – and made tons of money off it*, Vox (Sept. 22, 2016, 3:00 PM), http://www.vox.com/2016/2/5/10919360/opioidepidemic-chart.

233. The nation is experiencing an unprecedented opioid addiction and overdose epidemic, costing millions in health insurance and public safety spending, as well as lost productivity in the workforce.

234. In 2012 alone, an estimated 259 million opioid prescriptions were filled, enough to medicate every adult in the United States for a month on a round-the-clock basis.[119] The use of prescription painkillers cost health insurers up to $72.5 billion annually in direct healthcare costs.[120]

C. The Manufacturing Defendants' and Co-Conspirators' Specific Unlawful Practices that Targeted Prescribers Nationwide.

1. The Purdue Co-Conspirators

235. Purdue manufactures, markets, sells, and distributes opioids in nationwide, including the following:

OxyContin (oxycodone Hydrochloride extended release)	Opioid agonist[121] indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment; not indicated as an as-needed (p.r.n.) analgesic. It was first approved by the FDA in December 1995.	Schedule II

[119] *Opioid Painkiller Prescribing*, Centers for Disease Control and Prevention: Vital Signs (July 2014), https://www.cdc.gov/vitalsigns/opioid-prescribing/.
[120] Katherine Eban, *OxyContin: Purdue Pharma's painful medicine*, Fortune Magazine (Nov. 9, 2011), http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/ (hereinafter, "Eban, *Painful Medicine*").
[121] An "agonist" medication is one that binds to and fully activates targeted receptors in the brain. They activate these neurotransmitter receptors to elicit a certain response. An "antagonist" medication, on the other hand, works to prevent the binding of other chemicals to neurotransmitters in order to block a certain response. Both may be used to offer pain relief. *Health Q&A*, Reference*, https://www.reference.com/health/difference-between-agonist-antagonist-drugs-838e9e0994a788eb?aq=difference+between+agonist+and+antagonist&qo=cdpArticles (last visited Sept. 17, 2019).

MS Contin (morphine sulfate extended release)	Opioid agonist; controlled-release tablet form of morphine sulfate indicated for the management of severe pain; not intended for use as a p.r.n. analgesic; first approved in May 1987 as the first formulation of an opioid pain medicine that allowed dosing every 12 hours.	Schedule II
Dilaudid (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral formulation; eight times more potent than morphine.160	Schedule II
Dilaudid-HP (hydromorphone hydrochloride)	Opioid analgesic; injectable and oral high-potency and highly concentrated formulation indicated for relief of moderate-to-severe pain in opioid-tolerant patients.	Schedule II
Hysingla ER (hydrocodone bitrate)	Brand-name extended-release form of hydrocodone bitrate indicated for the management of severe pain.	Schedule II
Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride)	Brand-name extended-release opioid analgesic made of a combination of oxycodone hydrochloride and naloxone hydrochloride. It was approved by the FDA on July 23, 2013.	Schedule II

a) Purdue Falsely Marketed Extended-Release Drugs as Safer and More Effective than Regular-Release Drugs.

236. At all relevant times, members of the Sackler Family – Richard Sackler, Jonathan Sackler, Mortimer Sackler, Kathe Sackler, Beverly Sackler, Theresa Sackler, Ilene Sackler Lefcourt, David Sackler and the Raymond Sackler Trust – controlled Purdue and its related entities. This small group became extraordinarily wealthy because of their positions within Purdue and wielded immense power. Rather than use this power in a lawful and responsible manner, the Sacklers directed and oversaw Purdue's deceptive and unlawful sales and marketing practices.

237. The small and closely-held nature of Purdue and its associated entities makes the companies, in effect, the personal enterprises of the Sacklers. The Sacklers beneficially own and direct all the associate companies of Purdue in essentially the same manner as Purdue itself is controlled. All of Purdue's profits from opioids go to Sackler Family trusts and entities.

238. The Sacklers caused Purdue and associate companies that they owned and controlled to distribute hundreds of millions of dollars in profit from the sale of opioids.

239. Because the Sacklers control Purdue's board, the officers of the company report directly to them, ensuring the Sacklers' control even if the company's officers were not themselves members of the families.

240. Each of the Sacklers named in this complaint has served on the board of directors of Purdue, and some of them have also served as officers of Purdue and/or one or more Purdue related associate companies.

241. Purdue launched OxyContin 20 years ago with a bold marketing claim: "One dose relieves pain for 12 hours, more than twice as long as generic medications."[122] Prior to launching OxyContin, Purdue conducted focus groups with doctors and "learned that the 'biggest negative' that might prevent widespread use of the drug was ingrained concern regarding the 'abuse potential' of opioids."[123] In its initial press release launching the drug, Purdue told doctors that one OxyContin would provide "smooth and sustained pain control all day and all night." Based in large part on that promise, and on Purdue's repeated assurances that opioids were both effective and non-addictive, OxyContin became America's bestselling painkiller.[124] Purdue had no evidentiary basis for those claims.[125]

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[122] Harriet Ryan et al., *"You Want A Description of Hell?" OxyContin's 12-Hour Problem*, L.A. Times (May 5, 2016), http://www.latimes.com/projects/oxycontin-part1/ (hereinafter, "Ryan, *Description of Hell*").

[123] Keefe, *Empire of Pain*, *supra* n.27.

[124] Press Release, Purdue Pharma L.P., New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain (May 31, 1996), http://documents.latimes.com/oxycontin-press-release-1996/.

[125] Though the FDA's 1995 approval allowed Purdue to include a package insert for OxyContin declaring the drug to be safer than its competitors due to its delayed release design, Purdue had in fact "conducted no clinical studies on how addictive or prone to abuse the drug might be. . . The F.D.A. examiner who oversaw the process, Dr. Curtis Wright, left the agency

242. In truth, Purdue's nationwide marketing claims were false and highly deceptive. OxyContin was not superior to immediate-release opioids. And not only does OxyContin wear off early, as Purdue's own early studies showed, it is highly addictive.[126]

243. Furthermore, experts call the 12-hour dosing "'an addiction producing machine.'" Purdue had reportedly known for decades that it falsely promised 12-hour relief but nevertheless mobilized hundreds of sales representatives to "refocus" physicians on 12-hour dosing:

- Even before OxyContin went on the market, *clinical trials showed many patients weren't getting 12 hours of relief*. Since the drug's debut in 1996, the company has been confronted with additional evidence, including complaints from doctors, reports from its own sales reps and independent research.

- The company has held fast to the claim of 12-hour relief, in part to protect its revenue. OxyContin's market dominance and its high price – up to hundreds of dollars per bottle – hinge on its 12-hour duration. Without that, it offers little advantage over less expensive painkillers.

- When many doctors began prescribing OxyContin at shorter intervals in the late 1990s, Purdue executives mobilized hundreds of sales reps to "refocus" physicians on 12-hour dosing. Anything shorter "needs to be nipped in the bud. NOW!!" one manager wrote to her staff.

- Purdue tells doctors to prescribe stronger doses, not more frequent ones, when patients complain that OxyContin doesn't last 12 hours. That approach creates risks of its own. Research shows that the more potent the dose of an opioid such as OxyContin, the greater the possibility of overdose and death.

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shortly afterward. Within two years, he had taken a job at Purdue." Keefe, *Empire of Pain*, *supra* n.27.

[126] The *Los Angeles Times* investigation, reported in three parts on May 5, July 10 and December 18, 2016, included the review of thousands of pages of confidential Purdue documents and court and other records. They span three decades, from the conception of OxyContin in the mid-1980s to 2011, and include e-mails, memoranda, meeting minutes and sales reports, as well as sworn testimony by executives, sales representatives and other employees. Ryan, *Description of Hell*, *supra* n.122. The *Los Angeles Times* reporters also examined FDA records, Patent Office files and medical journal articles, and interviewed experts in pain treatment, addiction medicine and pharmacology. *Id.*

- More than half of long-term OxyContin users are on doses that public health officials consider dangerously high, according to an analysis of nationwide prescription data conducted for the *Los Angeles Times*.[127]

244. As reported by *The New York Times*, "internal Purdue Pharma documents show that company officials recognized even before the drug was marketed that they would face stiff resistance from doctors who were concerned about the potential of a high-powered narcotic like OxyContin to be abused by patients or cause addiction." To combat this resistance, Purdue promised the long-acting, extended-release formulation as safer and "less prone to such problems."[128]

245. Purdue's sales culture nationwide required aggressive sales of its opioids and embraced the sell-at-any-cost notion: "sell or be gone." Aggressive quotas were put into place for opioids including OxyContin, at all dosage levels, as well as Hysingla products. The highest dosage for OxyContin was referred to by Purdue sales representatives as "hillbilly heroin." When sales representatives failed to meet their quotas, they were placed on performance employment plans and/or terminated. When they were successful, they were richly rewarded with extravagant bonuses and prizes.

246. For Purdue, sales grew from $48 million per year in 1996, to over $1 billion per year in 2000, and to $3.1 billion per year ten years later. In 2011, pharmaceutical companies generated revenues of $11 billion from opioid sales alone.

247. By 2002, "[l]ifetime ***nonmedical*** use of OxyContin increased from 1.9 million to 3.1 million people between 2002 and 2004, and in 2004 there were 615,000 new nonmedical

[127] Ryan, *Description of Hell*, *supra* n.122.
[128] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html (hereinafter, "Meier, *Guilty Plea*").

users of OxyContin."[129] "[B]y 2004 OxyContin had become a leading drug of abuse in the United States."[130]

248. As OxyContin sales grew between 1999 and 2002, so did sales of other opioids, including fentanyl (226%), morphine (73%), and oxycodone (402%). And, as prescriptions surged between 1999 and 2010, so did deaths from opioid overdoses (from about 4,000 to almost 17,000).[131]

b) Purdue Falsely Marketed Low Addiction Risk to Wide Swaths of Physicians.

249. In addition to pushing OxyContin as safe and non-addictive by equating extended-release with a lower risk, Purdue also promoted the use of prescription opioids for use in non-cancer patients, who make up 86% of the total opioid market today.[132]

250. Rather than targeting merely those physicians treating acute, severe short-term pain, like physicians or oncologists treating post-operative or end-stage cancer pain, reports indicate that Purdue heavily promoted OxyContin nationwide to doctors such as general practitioners, who often had little training in the treatment of serious pain or in recognizing signs of drug abuse in patients.[133] According to a report in *The New Yorker*, "[a] major thrust of the sales campaign was that OxyContin should be prescribed not merely for the kind of severe short-term pain associated with surgery or cancer but also for less acute, longer-lasting pain: arthritis, back pain, sports injuries, [and] fibromyalgia," such that "[t]he number of conditions that OxyContin could treat seemed almost unlimited."[134]

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[129] Van Zee, *Promotion and Marketing*, *supra* n.41.
[130] *Id.*
[131] Gounder, *Who Is Responsible*, *supra* n.47.
[132] Ornstein, *American Pain Foundation*, *supra* n.71.
[133] Meier, *Guilty Plea*, *supra* n.128.
[134] Keefe, *Empire of Pain*, *supra* n.27.

251. Sales representatives plied these and other physicians with coupons that were redeemable for a 7- to 30-day supply of free OxyContin, a Schedule II narcotic that by definition cannot be prescribed for more than one month at a time, with the promise that OxyContin was a safe opioid. Purdue "trained its sales representatives to carry the message that the risk of addiction was 'less than one percent," and "[a] consistent feature in the promotion and marketing of OxyContin was a systematic effort to minimize the risk of addiction in the use of opioids for the treatment of chronic noncancer-related pain."[135]

252. Sales representatives marketed OxyContin as a product "to start with and to stay with," and Purdue deliberately exploited a misconception it knew many doctors held that oxycodone was less potent than morphine.[136] Sales representatives also received training in overcoming doctors' concerns about addiction with talking points they knew to be untrue about the drug's abuse potential. *The New Yorker* reported that "[i]n 2002, a sales manager from the company, William Gergely, told a state investigator in Florida that Purdue executives 'told us to say things like it is "virtually" non-addicting.'"[137]

253. Further, "[a]ccording to training materials, Purdue instructed sales representatives to assure doctors – repeatedly and without evidence – that 'fewer than one per cent' of patients who took OxyContin became addicted." But "[i]n 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen percent."[138]

254. Even as late as 2015, if not later, Purdue sales representatives were telling physicians OxyContin was addiction resistant and had abuse-deterrent properties.

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[135] Van Zee, *Promotion and Marketing*, *supra* n.41.
[136] Keefe, *Empire of Pain*, *supra* n.27.
[137] *Id.*
[138] *Id.*

255. Purdue also tracked physicians' prescribing practices by reviewing pharmacy prescription data it obtained from I.M.S. Health, a company that buys bulk prescription data from pharmacies and resells it to drug makers for marketing purposes. (Notably, Arthur Sackler, who along with his brothers, Mortimer and Raymond, founded the Sackler family pharmaceutical businesses, co-founded I.M.S. Health.) Rather than reporting highly suspicious prescribing practices, Purdue used the data to track physicians who prescribed some opioids and might be persuaded to prescribe more. Purdue also could identify physicians writing large numbers of prescriptions, and particularly for high-dose 80 mg pills – potential signs of diversion and drug dealing.[139] It called the high-prescribing doctors "whales."[140]

256. Purdue knew about many suspicious doctors and pharmacies from prescribing records, pharmacy orders, field reports from sales representatives and, in some instances, its own surveillance operations.[141] Since 2002, Purdue has maintained a confidential roster of suspected reckless prescribers known as "Region Zero." By 2013, there were more than 1,800 doctors in Region Zero, but Purdue had reported only 8% of them to authorities. The *Los Angeles Times*

[139] An 80 mg tablet is equivalent in strength to 16 Vicodin tablets, and was generally reserved by doctors for patients with severe, chronic pain who had built up a tolerance over months or years. In the illegal drug trade, however, "80s" were the most in demand. For those attempting to detect how OxyContin was getting onto the black market, a physician writing a high volume of 80s was a red flag. Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, L.A. Times (July 10, 2016), https://www.latimes.com/projects/la-me-oxycontin-part2/ (hereinafter, "Ryan, *More than 1 million*").

[140] Keefe, *Empire of Pain*, *supra* n.27.

[141] Purdue's "Abuse and Diversion Detection" program requires its sales representatives to report to the company any facts that suggest a healthcare provider to whom it markets opioids may be involved in the abuse or illegal diversion of opioid products. When a provider is reported under the program, Purdue purportedly conducts an internal inquiry regarding the provider to determine whether he or she should be placed on a "no-call" list. If a provider is placed on this list, Purdue sales representatives may no longer contact the provider to promote the company's opioid products. Bill Fallon, *Purdue Pharma agrees to restrict marketing of opioids*, Stamford Advocate (Aug. 25, 2015, 3:32 PM), http://www.stamfordadvocate.com/business/article/Purdue-Pharma-agrees-to-restrictmarketing-of-6464800.php.

reported that "[a] former Purdue executive, who monitored pharmacies for criminal activity, acknowledged that even when the company had evidence pharmacies were colluding with drug dealers, it did not stop supplying distributors selling to those stores."[142]

c) Purdue Funded Publications and Presentations with False and Misleading Messaging.

257. As explained above, Purdue's false marketing scheme did not end with its own sales representatives and branded marketing materials. It extended far beyond, engaging third parties, including doctors and front groups, to spread the false message of prescription opioids' safety and efficacy.

258. Purdue caused the publication and distribution of false and deceptive guidelines on opioid prescribing. For example, as set forth above, Purdue paid $100,000 to the FSMB to help print and distribute its guidelines on the use of opioids to treat chronic pain to ***700,000*** practicing doctors.

259. One of the advisors for Fishman's 2007 publication, "Responsible Opioid Prescribing: A Physician's Guide," and its 2012 update, was Haddox, a longtime member of Purdue's speakers' bureau who later became a Purdue vice president.

260. Similarly,[143] multiple videos feature Fine delivering educational talks about the drugs. In one video from 2011 titled, "Optimizing Opioid Therapy," he sets forth a "Guideline for Chronic Opioid Therapy," discussing "opioid rotation" (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person's "lifetime" to manage pain.[144] He states the "goal is to improve

[142] Ryan, *More than 1 million*, *supra* n.139.
[143] Weber, *Two Leaders in Pain*, *supra* n.108.
[144] Perry A. Fine, *Safe and Effective Opioid Rotation*, YouTube (Nov. 8, 2012), https://www.youtube.com/watch?v=_G3II9yqgXI.

effectiveness which is different from efficacy and safety." Rather, for chronic pain patients, effectiveness "is a balance of therapeutic good and adverse events *over the course of years*." The entire program assumes that opioids are appropriate treatment over a "protracted period of time" and even over a patient's entire "lifetime." He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with "tools," but leaves that for "a whole other lecture."[145]

261. Purdue provided many "teaching" materials free of charge to the Joint Commission.

262. Purdue also deceptively marketed the use of opioids for chronic pain through the APF. Purdue paid the APF unspecified amounts in 2008 and 2009 and between $100,000 and $499,999 in 2010.[146]

d) The Guilty Pleas.

263. In May 2007, Purdue and three of its executives pled guilty to federal charges of misbranding OxyContin and falsely marketing and promoting OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal symptoms than other pain medications, in what the company acknowledged was an attempt to mislead doctors. Purdue was ordered to pay $600 million in fines and fees. In its plea, Purdue admitted that its promotion of OxyContin was misleading and inaccurate, misrepresented the risk of addiction, and was unsupported by science. Additionally, Michael Friedman ("Friedman"), the company's president, pled guilty to a misbranding charge and agreed to pay $19 million in fines; Howard R.

[145] *Id.*

[146] American Pain Foundation, 2010 Annual Report at 16-19, https://assets.documentcloud.org/documents/277604/apf-2010-annual-report.pdf (last visited Dec. 15, 2018). Defendants Endo, Cephalon, and Janssen also made substantial payments to the APF in 2010: Endo more than $1 million, Cephalon between $50,000 and $99,999, and Janssen between $1,000 and $49,999. *Id.* at 19.

Udell ("Udell"), Purdue's top lawyer, pled guilty and agreed to pay $8 million in fines; and Paul D. Goldenheim ("Goldenheim"), its former medical director, pled guilty and agreed to pay $7.5 million in fines.

264. In a statement announcing the guilty plea, John Brownlee ("Brownlee"), the U.S. Attorney for the Western District of Virginia, stated:

> Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. *Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.*
>
> *But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures*. . . . OxyContin was the child of marketers and bottom line financial decision making.[147]

265. Brownlee characterized Purdue's criminal activity as follows:

> First, *Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse*. Purdue ordered this training even though its own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.
>
> Second, *Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction* than immediate release opioids.
>
> Third, *Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate release opioids resulting in less euphoria and less potential for abuse* than short-acting opioids.

[147] Press Release, U.S. Department of Justice, Statement of United States Attorney John Brownlee on the Guilty Plea of the Purdue Frederick Company and Its Executives for Illegally Misbranding OxyContin (May 10, 2007), https://www.ctnewsjunkie.com/upload/2016/02/usdoj-purdue-guilty-plea-5-10-2007.pdf.

> Fourth, *Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance* to the drug.
>
> And fifth, *Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids*, and could be used to "weed out" addicts and drug seekers.[148]

266. Specifically, Purdue pled guilty to illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers, while Friedman, Udell, and Goldenheim pled guilty to the misdemeanor charge of misbranding OxyContin by introducing it into interstate commerce in violation of 21 U.S.C. §§331(a), 333(a)(1)-(2) and 352(a).

267. In 2019, the New York Times reported that a charging memo from the investigation, which was never released, confirmed that Purdue knew as early as 1996 that OxyContin was dangerously addictive and took steps to suppress that information.[149] This was despite the fact that Howard Udell, Purdue's General Counsel, testified in Congress and elsewhere that the company was unaware until early 2000 that OxyContin was being abused.[150]

268. Nevertheless, even after the settlement, Purdue continued to pay doctors on speakers' bureaus to promote the liberal prescribing of OxyContin for chronic pain and to fund seemingly neutral organizations to disseminate the message that opioids were effective and non-addictive, and continued to aggressively market the liberal prescribing of opioids for chronic pain while diminishing the associated dangers of addiction. After Purdue made its guilty plea in 2007,

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[148] *Id*.
[149] John Pappas, Producer, The Weekly: Episode 10: The Memo, NYTIMES (Apr. 16, 2019), https://www.nytimes.com/2019/08/16/the-weekly/opioid-crisis-epidemic.html.
[150] Barry Meier, *Origins of an Epidemic: Purdue Pharma Knew Its Opioids Were Widely Abused*, NYTIMES (May 29, 2018), https://www.nytimes.com/2018/05/29/health/purdue-opioids-oxycontin.html.

> it assembled an army of lobbyists to fight any legislative actions that might encroach on its business. Between 2006 and 2015, Purdue and other painkiller producers, along with their associated nonprofits, spent nearly nine hundred million dollars on lobbying and political contributions – eight times what the gun lobby spent during that period.[151]

269. Purdue has earned more than $35 billion from OxyContin, the nation's bestselling painkiller.[152] The Sackler family received at least $8 billion in company profits during that time.[153]

270. Purdue also made payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance, and other services.

e) The Sacklers Establish Rhodes as a "Landing Pad" from Purdue.

271. In or around November 2007, in the immediate aftermath of the guilty plea by Purdue and its executives regarding the company's false and misleading marketing of OxyContin, the Sacklers established Rhodes Pharmaceuticals. According to a former senior manager at Purdue, "Rhodes was set up as a 'landing pad' for the Sacklers in 2007, to prepare for the possibility that they would need to start afresh following the crisis then engulfing OxyContin."[154]

272. The Sacklers' involvement in Rhodes and its relationship to Purdue was not publicly known until the September 9, 2018 publication of an article in the *Financial Times*.

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[151] Keefe, *Empire of Pain*, *supra* n.27.
[152] Laura Strickler, Purdue Pharma offers as much as $12 billion to settle opioid suits, NBC News (Aug. 27, 2019), https://www.nbcnews.com/news/us-news/purdue-pharma-offers-10-12-billion-settle-opioid-claims-n1046526.
[153] David Armstrong and Jeff Ernsthausen, Data Touted by OxyContin Maker to Fight Lawsuits Doesn't Tell the Whole Story, ProPublica, https://www.propublica.org/article/data-touted-by-oxycontin-maker-to-fight-lawsuits-doesnt-tell-the-whole-story.
[154] David Crow, *How Purdue's 'one-two' punch fuelled the market for opioids*, Financial Times (Sept. 9, 2018), https://www.ft.com/content/8e64ec9c-b133-11e8-8d14-6f049d06439c.

According to the article, "Rhodes has not been publicly connected to the Sackler family before, and their ownership of the company may weaken one of their longstanding defenses: that they cannot be held responsible for the opioid crisis because Purdue accounts for a small fraction of the overall prescriptions."[155]

273. Despite being registered as a separate company from Purdue, staff from Rhodes and Purdue use the same employee handbook and "little distinction is made internally between the two companies."[156]

274. Rhodes manufactures, markets, sells, and distributes the following opioids nationwide:

Hydromorphone hydrochloride	Generic opioid agonist.[157]	Schedule II
Hydrocodone bitartrate and acetaminophen	Generic opioid agonist.	Schedule II
Oxycodone and acetaminophen	Generic opioid agonist.	Schedule II
Buprenorphine hydrochloride	Generic opioid agonist indicated for the treatment of opioid dependence.	Schedule III
Morphine sulfate	Generic opioid agonist.	Schedule II
Oxycodone hydrochloride	Generic opioid agonist.	Schedule II
Tapentadol hydrochloride	Generic opioid agonist.	Schedule II

275. According to the *Financial Times*, in 2016, Rhodes had a substantially larger share of prescriptions in the U.S. prescription opioid market than Purdue.[158]

[155] *Id.*
[156] *Id.*
[157] An agonist is a drug that activates certain receptors in the brain. Full agonist opioids activate the opioid receptors in the brain fully resulting in the full opioid effect. Examples of full agonists include heroin, oxycodone, methadone, hydrocodone, morphine, opium, and others.
[158] *Id.*

f) Purdue Failed to Monitor and Report Suspicious Sales as Required.

276. The Controlled Substances Act and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq*., impose on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and require the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

277. Purdue is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

278. Purdue failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Purdue also failed to report to the Board sales of dangerous drugs subject to abuse. Purdue's failure to timely report these and other suspicious sales violated the CSA.

2. The Sackler Family Co-Conspirators

a) The Individual Sacklers Direct and Control Purdue.

279. Richard Sackler is one of the six inventors listed on the original patent for OxyContin. He began working for Purdue in the 1970s as an assistant to his father, Raymond Sackler, who served as the president of the company at that time. Richard rose through leadership in the subsequent decades, serving as President of Purdue from 1999 to 2003.

280. Richard Sackler resigned from his role in 2013 over apparent worry that executive officers of Purdue would be held personally liable for any opioid-related liabilities. He continued

to serve as co-chair of Purdue's board with his uncle, Mortimer Sackler. This allowed the Sacklers to retain control of the company regardless of their involvement at the executive level.

281. During his executive tenure at Purdue, Richard Sackler actively participated in nearly every aspect of the company's opioid products, from invention to marketing to sale. With the assistance of his father, Raymond, and his uncle, Mortimer, Richard introduced OxyContin to the market with one of the largest pharmaceutical advertising campaigns in history. Within five years, OxyContin was earning Purdue $1 billion a year.

282. At all relevant times, Richard Sackler served as trustee of one or more trusts that own and control Purdue or Purdue-associated companies. He is the direct or indirect beneficiary of some portion of 25% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

283. Jonathan Sackler served as Senior Vice President of Purdue by 2000. Like Richard, his brother, Jonathan resigned from his position in or after 2003, due to concerns that the executive officers of Purdue would be personally liable for crimes and litigation stemming from Purdue's opioid products. Jonathan continued to serve on Purdue's board after his resignation.

284. At all relevant times, Jonathan Sackler served as trustee of one or more trusts that own and control Purdue or Purdue-associated companies. He is the direct or indirect beneficiary of some portion of 25% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

285. Mortimer Sackler is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

286. Kathe Sackler, Mortimer's daughter, began serving as Senior Vice President of Purdue by 2000. She resigned from her position in or about 2003 due to concerns that the executive officers of Purdue could be held personally liable for crimes and litigation stemming from Purdue's opioid products. She continued to serve on Purdue's board. She is the direct or indirect beneficiary of 7.14% of the profits earned from the sale of opioids by Purdue and the Purdue-associated companies listed herein.

287. Ilene Sackler Lefcourt, another of Mortimer's daughters, served as Vice President of Purdue during the initial development and launch of OxyContin. She, too, resigned from her position around 2003 due to concerns of personal liability for executive officers of Purdue for opioid-related crime and litigation, but continued to serve on the board.

288. Beverly Sackler, Raymond's wife, has served on the Board of Directors of Purdue and associated entities since the 1990s. She serves as the trustee of one or more trusts that own or control Purdue and Purdue associated companies, and to which 50% of the profits of the companies' sale of opioids have been conveyed. She is the direct or indirect beneficiary of some portion of the 50% of profits earned by Purdue through the sale of opioids.

289. Theresa Sackler, Mortimer's wife, has served on the Board of Directors of Purdue and associated entities since the 1990s. She is the direct or indirect beneficiary of some portion of the 50% of profits earned by Purdue through the sale of opioids.

290. David Sackler, Richard's son, has served on the Board of Directors of Purdue and associated entities since 2012. He is the direct or indirect beneficiary of some portion of 25% of the profits earned by Purdue through the sale of opioids.

291. Richard Sackler, Jonathan Sackler, Mortimer Sackler, Kathe Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David Sackler, and the Raymond Sackler

Trust (through its trustees) each knowingly aided, participated in, and benefited from the unlawful conduct of Purdue.

b) The Sacklers Oversee and Direct Purdue's Unlawful Conduct.

292. Arthur Sackler, the brother of Raymond and Mortimer Sackler, is largely responsible for the change in public perception with regard to the purportedly safe uses of opioids. He was a psychiatrist and investor who effectively created the modern pharmaceutical advertising industry. He realized that direct advertising to doctors and prescribers would be the most effective means of turning a profit. He paid prominent doctors to endorse his products, offered physicians perks and benefits, published marketing material disguised as neutral medical journal articles, and funded "education" seminars that extolled the virtues of his drug products. His deceptive and unethical marketing techniques led to Valium becoming the first hundred-million-dollar, then billion-dollar, prescription drug and set the precedent for the current problems with pharmaceutical marketing.

293. The Sacklers have continued to direct Purdue's unlawful marketing techniques, using many of the same unethical techniques developed by Arthur Sackler in order to maximize their sales of opioid products.

294. OxyContin was launched with one of the largest pharmaceutical marketing campaigns in history, with roughly 1,000 sales representatives touting the drug's benefits. Representatives would recommend OxyContin as the solution not just for acute, short-term pain, but also for less-acute, longer lasting pain. Sales training included lessons in overcoming doctors' concerns about health and addiction by minimizing or downplaying OxyContin's true qualities. Purdue paid thousands of physicians to present to medical conferences on the benefits of OxyContin.

295. The Sacklers were deeply involved in OxyContin's marketing campaign. Sacklers were on site at Purdue's headquarters daily, controlling the management of the family business. According to a former sales representative, Richard Sackler was "the dude that made it happen." In response to the concerns of benefit plans that OxyContin was ripe for addictive use, Richard sent an email to sales representatives, asserting that "'addiction' may be a convenient way for insurance companies to just say "NO" to coverage.[159]

296. In 1997, Richard and Kathe Sackler took part in a conspiracy to mislead doctors by claiming oxycodone was half as strong as morphine when the opposite was the case. Purdue engaged in this deception to alleviate the fears of medical professionals in prescribing the drug for non-acute pain.

297. Around 1999 to 2003, Purdue had a system where company emails would self-erase after pre-determined times. This policy created a system where potentially incriminating documents would be automatically erased even if received by third parties. Richard, Jonathan, and Kathe Sackler were all aware and supportive of this system.

c) Sacklers Were Aware of the Abuse Potential of OxyContin Since at Least 1996.

298. Purdue and the Sacklers were aware that OxyContin and other prescription medication could lead to addiction since at least 1996. Indeed, the inventor of OxyContin, Robert Kaiko, wrote to Richard Sackler to oppose the idea of selling OxyContin as a "non-narcotic." He warned, "I don't believe we have a sufficiently strong case to argue that OxyContin has minimal or no abuse liability." To the contrary, Kaiko wrote, "oxycodone containing products are still among the most abused opioids in the U.S.," and he predicated: "If OxyContin is uncontrolled,

[159] Keefe, *Empire of Pain*, *supra* n.27.

… it is highly likely that it will eventually be abused." Richard responded: "How substantially would it improve your sales?"[160]

299. In 1997, Richard Sackler, Kathe Sackler, and other Purdue executives determined that doctors had the misconception that OxyContin was weaker than morphine, which led them to prescribe it more often, even as a substitute for Tylenol. Richard Sackler ordered Purdue staff not to correct the misconception, because it could harm OxyContin's sales.[161]

300. In 1999, an internal memo prepared by Purdue employee Maureen Sara described the abuse and recreational use of OxyContin. The memo was sent directly to Purdue's board members, including Richard, Jonathan, and Kathe Sackler.

301. In spite of the 1999 memo, Purdue President Michael Friedman testified before the U.S. House of Representatives in 2001 that Purdue had not become aware of OxyContin's potential for abuse until 2000. None of the Sacklers or anyone else at Purdue attempted to correct this false narrative.

302. The Sacklers were thus aware of potential liability for Purdue, since at least 1999, due to OxyContin's addictive nature. Instead of attempting to fix or solve the issue they had created, the Sacklers began to transfer profits from Purdue and associated companies to their own private trusts and accounts in order to shield their funds from creditors. In 2015, for example, the Sacklers removed $700 million from their privately held companies, two-thirds of which came from Purdue. These transfers of ill-gotten gains were and are fraudulent, unjustly enriched the Sacklers, and were done for the purpose of protecting the money from any civil or

[160] Complaint, *Commonwealth of Mass v. Purdue Pharma L.P., et al.*, C.A. No. 1884-cv-01808 (BLS2), ¶ 174 (Mass Supr. Ct. Jan. 31, 2019) (hereinafter "Mass Complaint"), https://assets.documentcloud.org/documents/5716943/Massachusetts-AGO-Amended-Complaint-2019-01-31.pdf.
[161] *Id.* at ¶ 176.

criminal judgment against Purdue for its participation in the opioid crisis. These transfers also left Purdue and its associated entities undercapitalized and potentially unable to pay a judgment against it in this litigation.

303. In 2001, Richard Sackler received word from a Purdue sales representative that he had attended a community meeting at a local high school organized by mothers whose children overdosed on OxyContin and died. "Statements were made that OxyContin sales were at the expense of dead children and the only difference between heroin and OxyContin is that you can get OxyContin from a doctor."[162]

304. In 2001, a federal prosecutor reported 59 deaths from OxyContin in a single state. Richard Sackler wrote to Purdue executives: "This is not too bad. It could have been far worse."

305. In March, 2001, the New York Times and Time Magazine published articles about widespread deaths related to OxyContin.[163]

306. The next month, Richard Sackler wrote in an email his strategy for discounting the overwhelming evidence that OxyContin caused widespread abuse and death: "we have to hammer on the abusers in every way possible. They are the culprits and the problem. They are reckless criminals."[164]

307. That spring, Purdue executives met with the DEA. A senior DEA official, who sat across from Rickard Sackler, leaned over the table and told him: "People are dying. Do you understand that?"[165]

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[162] *Id*. at ¶ 181.
[163] *See* Barry Meier, *Sales of Painkiller Grew Rapidly, But Success Brought a High Cost*, NYTimes (Mar. 5, 2001), https://www.nytimes.com/2001/03/05/business/sales-of-painkiller-grew-rapidly-but-success-brought-a-high-cost.html.
[164] *Id*. at ¶ 183.
[165] Barry Meier, Pain Killer: A "Wonder" Drug's Trail of Addiction and Death, Rodale (2003).

308. In March 2013, staff reported to the Sacklers on the devastation caused by prescription opioids. Staff told the Sacklers that drug overdose deaths had more than tripled since 1990—the period during which Purdue had made OxyContin the best-selling painkiller. They told the Sacklers that tens of thousands of deaths were only the "tip of the iceberg," and that, for every death, there were more than a hundred people suffering from prescription opioid dependence or abuse.

309. Just two months later, at a May 2013 board meeting, staff reported to the Sacklers that they were successfully pushing opioid savings cards through direct mail and email to get patients to "remain on therapy longer."

d) The Sacklers' Full Understanding Of Opioid Abuse And Addiction Risk is Underscored By Their Pursuit of Business Opportunities In Medications That Treat Addiction Their Own Opioids Caused.

310. In 2007, Richard Sackler applied for a patent to treat opioid addiction. He finally received it in January 2018 and assigned it to Rhodes, the "landing pad" company set up and controlled by the Sacklers, instead of Purdue. Richard's patent application says opioids are addictive. The application calls the people who become addicted to opioids "junkies" and asks for a monopoly on a method of treating addiction.

311. In September 2014, Kathe Sackler participated in a call about Project Tango—a plan for Purdue to expand into the business of selling drugs to treat opioid addiction. In their internal documents, defendant Kathe Sackler and staff memorialized what Purdue had publicly denied for decades: "Pain treatment and addiction are naturally linked." The team reviewed findings that the "market" of people addicted to opioids had doubled from 2009 to 2014.

312. Kathe Sackler ordered staff's "immediate attention, verification, and assessment" of reports that children requiring hospitalization after swallowing a film that melts in your

mouth, and staff assured Kathe that children were overdosing on pills like OxyContin, not films, "which was positive for Tango."

313. In February 2015, staff presented Kathe Sackler's work on Project Tango to Purdue's board. The plan was for a joint venture controlled by the Sacklers to sell the addiction medication suboxone and would result in the Sackler's acquisition of a substantial share of the addiction medicine market.

314. During the presentation, the Tango team mapped how patients could get addicted to opioids through prescription opioid analgesics such as Purdue's OxyContin or heroin, and then become consumers of the new company's suboxone. The team noted the opportunity to capture customers: even after patients were done buying suboxone the first time, 40-60% would relapse and need it again.

315. In June 2016, the Sacklers met to discuss a revised version of Project Tango and considered a scheme to sell the overdose antidote NARCAN. At this meeting, the Sacklers and the Purdue board calculated that the need for NARCAN to reverse overdoses could provide a growing source of revenue, tripling from 2016 to 2018.

316. The Sacklers identified patients on Purdue's prescription opioids as the target market for NARCAN. Their plan called for studying "long-term script users" to "better understand target end-patients" for NARCAN. The Sacklers planned to "leverage the current Purdue sales force" to "drive direct promotion to targeted opioid prescribers" and determined that Purdue could profit from government efforts to use NARCAN to save lives.

317. In December 2016, Richard, Jonathan and Mortimer Sackler had a call with staff regarding yet another version of Project Tango to discuss acquiring a company that treated opioid addiction with implantable drug pumps. The business was a "strategic fit," because

Purdue sold opioids and the new business treated the "strategically adjacent indication of opioid dependence."

318. In September 2019, two years after these MDL proceedings began, the same week that Purdue and the Sacklers reached a tentative settlement with 23 states and thousands of local governments, and less than one week before Purdue filed for bankruptcy, the New York attorney general's office disclosed that it had uncovered about $1 billion in secret, previously undisclosed wire transfers between the Sackler family and international financial institutions, suggesting the Sacklers were engaged in stashing their wealth in overseas bank accounts to attempt to conceal them from consideration in the pending litigation and preliminary settlement .[166]

e) The Sacklers Continued to Oversee Purdue's Wrongdoing Even After Repeated Warnings and Fines.

319. The liability of the Sacklers extends beyond their leadership of Purdue. They were aware of, and obligated to address, Purdue's conduct due to previous investigations into the company's deceptive practices.

320. Purdue Pharma Inc. and Purdue Pharma L.P. were under investigation by 26 states and the DOJ from 2001 to 2017. In 2003, on the advice of legal counsel, every Sackler who held an executive role at Purdue resigned to avoid personal liability for the conduct in which they had engaged and continued to engage prior to and after their resignations. But the Sacklers retained ownership and control of the company.

321. In 2007, the directors of Purdue Pharma Inc. declared that it would pay roughly $700 million and plead guilty to a felony for misleading doctors and patients about opioid medications. (The company that paid the money, the Purdue Frederick Company, was the

[166] Deanna Paul, *N.Y. attorney general exposes $1 billion in wire transfers by Sackler family*, Washington Post (Sept. 14, 2019) https://www.washingtonpost.com/business/2019/09/14/ny-attorney-general-exposes-billion-wire-transfers-by-sackler-family/.

original pharmaceutical company purchased by Arthur Sackler and his brothers, and while it was technically a separate corporate entity, it was controlled by the same people and shared the same headquarters as Purdue Pharma L.P.). The company acknowledged that its supervisors and employees had fraudulently promoted OxyContin as safer and less addictive than other pain medications.

322. Michael Friedman, the Chief Executive Officer ("CEO") of Purdue, pled guilty to criminal charges of fraudulent marketing. Udell, Purdue's chief lawyer, and Goldenheim, Purdue's chief medical officer, pled guilty to the same crime.

323. The 2007 convictions warned the directors against any further deception.

324. The directors also agreed to a Consent Judgment that ordered Purdue not to make any false or misleading oral or written claims about OxyContin, including concerning the risk of addiction. The Consent Judgment also required Purdue to establish a program that would identify high-prescribing doctors, stop promoting OxyContin to them, and report them. This program was to last from 2007 to 2017.

325. The directors also entered a Corporate Integrity Agreement with the U.S. government, wherein Purdue would appoint a compliance officer to a senior management position at Purdue. The officer would make periodic reports on compliance matters to the board to ensure no deception took place again. Under the agreement, the directors and CEO were "Covered Persons" who had to comply with rules prohibiting deception regarding Purdue's products. This status lasted from 2007 to 2012 and required that leadership report all rule violations and undergo hours of compliance training. The directors and CEO were warned of consequences in case of a violation and certified that they understood their new status.

326. Purdue's directors were clearly aware of their obligations under the above agreements. In 2009, Purdue had to report to the Inspector General of the U.S. Department of Health and Human Services ("HHS") that it had not immediately trained a new director on the terms of the Corporate Integrity Agreement. Purdue assured the government that the director had undergone the training the day after Corporate Compliance had learned of the issue.

327. The years after the 2007 guilty plea and Corporate Integrity Agreement were filled with alarming reports and stories about the opioid crisis. However, in spite of these widespread warnings, Purdue's directors, including the Sacklers, did nothing to stop Purdue's misconduct.

328. From 2007 through 2018, the Sacklers controlled Purdue's deceptive sales campaign. They directed the company to hire hundreds more sales representatives, who visited doctors thousands more times. They insisted that sales representatives repeatedly visit the most prolific prescribers. They directed the representatives to encourage doctors to prescribe more of the highest doses of opioids. They studied unlawful tactics to keep patients on opioids longer and then ordered staff to use them. They asked for detailed reports about doctors suspected of misconduct, how much money Purdue made from them, and how few of them Purdue had reported to authorities. They sometimes demanded more detail than others in the entire company, so staff had to create special reports just for them. Richard Sacker even went into the field to promote opioids to doctors and supervise representatives personally.

329. The Sacklers' micromanagement was so intrusive that staff begged for relief. In fact, Purdue's Vice President of Sales and Marketing wrote to the CEO: "Anything you can do to reduce the direct contact of Richard into the organization is much appreciated."[167]

[167] Complaint, ¶ 54, *State of New Hampshire v. Richard Sackler, et al*., 217-2019-CV-00617 (N.H. Super. Ct. Sept. 16, 2019) (hereinafter "New Hampshire Complaint").

330. Upon information and belief, the Sacklers voted to direct Purdue to pay their family billions of dollars, including profits from opioids. These payments show the absolute control that the Sacklers exercised over Purdue.

331. On April 18, 2008, Richard Sackler sent Kathe, Jonathan, and Mortimer Sackler a memo about how to keep money flowing to their family. Richard wrote that Purdue's business posed a "dangerous concentration of risk." After the criminal investigations that almost reached the Sacklers, Richard wrote that it was crucial to install a CEO who would be loyal to the family: "People who will shift their loyalties rapidly under stress and temptation can become a liability from the owners' viewpoint." Richard recommended John Steward for CEO because of his loyalty. Richard also proposed that the family should either sell Purdue in 2008 or, if they could not find a buyer, milk the profits out of the business and "distribute more free cash flow" to themselves.[168]

332. That month, the Sacklers voted to have Purdue pay their family $50 million. From the 2007 convictions until 2018, the Sacklers voted dozens of times to pay out Purdue's opioid profits to their family—in total more than four billion dollars.[169]

333. In 2008, opioid overdoses killed more Americans in that year than any year prior.

334. In 2009, the *American Journal of Public Health* published "The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy."[170] The article detailed the misleading and deceptive nature of Purdue's opioid marketing, including the misuse of sales representatives, the targeting of high-prescribing practitioners. and deception about the potential

[168] *Id.* at ¶ 58.
[169] *Id.*
[170] Van Zee, *Promotion and Marketing, supra* n.41.

rates of abuse. The CDC reported that deaths stemming from opioid use had tripled in the preceding year.

335. In 2010, *Time* magazine published "The New Drug Crisis: Addiction by Prescription."[171] The article focused extensively on Purdue's line of opioid products. Overdoses were the number one cause of accidental death in 15 states that year, and Purdue's directors were informed that Purdue would not be able to get product liability insurance to cover OxyContin.

336. In 2011, the White House announced that prescription drug abuse was the nation's fastest-growing drug problem and called for educating healthcare providers about prescription drug abuse to prevent over prescription. The CDC announced that prescription opioid overdoses had reached never-before-seen levels and specifically called out Purdue's line of opioid products. *Fortune* magazine published an article that same year where Purdue executives were interviewed about the ongoing crisis and the involvement of the company and the Sacklers. The interviewees included Purdue Vice President Alan Must, who admitted that Purdue was "well aware" of concerns about its conduct: "We are well aware of detractors. For those individuals who think we're evil . . . I don't think there's anything we can do that is going to change their opinion."[172]

337. In 2012, the U.S. Senate announced an investigation into Purdue's unlawful deception of doctors and patients about the nature of its opioid products. The Senate specifically warned the directors and CEO that they were under scrutiny, demanding that Purdue present a set

[171] Jeffrey Kluger, *The New Drug Crisis: Addiction by Prescription*, TIME (Sept. 17, 2010), http://content.time.com/time/magazine/article/0,9171,2015763,00.html.
[172] Eban, *Painful Medicine*, *supra* n.120.

of "presentations, reports, and communications to Purdue's management team or board of directors from 2007 to the present."[173]

338. In 2013, the *Los Angeles Times* reported that Purdue had created a list of 1,800 doctors suspected of recklessly prescribing its opioids over the past decade but had reported only 8% of them to authorities. Purdue attorney Robin Abrams gave multiple interviews to the newspaper. Abrams was a Vice President of Purdue, and she signed Purdue's 2007 settlement agreement. In 2013, she admitted that Purdue had the list, and said with regard to Purdue's unwillingness to disclose the list: "I don't really want to open up an opportunity for folks [to] come in here and start looking and second guessing."[174]

339. Abrams and Purdue's directors had good reason to be concerned: the state of Kentucky had brought a lawsuit against Purdue for deceiving doctors and patients about the nature of its opioid products. When Purdue's lawyers surveyed the local residents for potential jury service, one-third of respondents said they knew someone who had been hurt or had overdosed taking Purdue opioids, and 29% knew someone who had died. Purdue itself filed these findings in court.

340. In 2014, Edward Mahony, the Executive Vice President, Chief Financial Officer, and Treasurer of Purdue, announced that the Kentucky lawsuit was noteworthy enough to "jeopardize Purdue's long-term viability."[175] The Governor of Massachusetts declared the opioid crisis a public health emergency in the same year.

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[173] May 8, 2012 Letter from U.S. Senators Charles E. Grassley and Max Baucus to John H. Stewart, President and CEO of Purdue Pharma, https://www.finance.senate.gov/imo/media/doc/Purdue_May_8.pdf.

[174] Scott Glover & Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, Los Angeles Times (Aug. 11, 2013), https://www.latimes.com/local/la-me-rx-purdue-20130811-story.html.

[175] Tracy Staton, *Addiction-riddled Kentucky out for blood in $1B suit against OxyContinmaker*

341. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO, including the Sackers, controlled the operation of Purdue's sales representatives. Director Richard Sackler testified that Purdue primarily promoted its opioids through its sales representatives, and that regular visits from representatives were the key to get doctors to continue to prescribe the drugs. The board knew which drugs the sales representatives were to promote, the number of visits representatives made to doctors, how much each visit cost the company and the quarterly plans for sales visits. The board approved specific hiring plans for their sales representatives, hiring directors and regional managers and creating sales territories for representatives to target doctors.

342. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO, including the Sacklers, oversaw the specific tactics used by sales representatives to sell opioids; for example, a board report encouraged the use of iPads during sales visits, which increased the average length of meetings to 16.7 minutes.

343. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO, including the Sacklers, oversaw the promotional claims representatives used during sales visits. The directors and CEO reviewed reports that Purdue sales representatives were deceptively promoting opioids as an appropriate treatment for minor pain, among hundreds of other examples of unlawful marketing techniques in need of correction.

344. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO, including the Sacklers, oversaw Purdue's research, which in some cases contradicted the company's marketing. Company leadership received detailed and specific reports concerning Purdue opioids being used for "opioid naïve" patients and patients with osteoarthritis.

Purdue, FiercePharma.com (Oct. 20, 2014), https://www.fiercepharma.com/pharma/addiction-riddled-kentucky-out-for-blood-1b-suit-against-oxycontin-maker-purdue.

345. Plaintiffs are informed and believe, and thereupon allege, that company leadership, including the Sacklers, was directly informed of "Reports of Concern" filed by sales representatives regarding high-prescribing doctors, as well as "field inquiries" in response to the reports.

346. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO, including the Sacklers, monitored sales representatives' emails. Purdue had a policy of prohibiting sales representatives from communicating with doctors via email; when Purdue found that some representatives had in fact e-mailed doctors, the company "investigated" the matter and told the board that the representatives had been disciplined and the matter would be discussed at the next board meeting.

347. Plaintiffs are informed and believe, and thereupon allege, that the directors, including the Sacklers, oversaw Purdue's strategy to pay high-prescribing doctors to promote its opioids. The board was aware of the amount paid to specific high prescribers and the return on investment it received from these payments. The board knew that Purdue allowed a gift spending limit of $750 per doctor per year and was told specifically that paying doctors was a high-risk activity that could result in improper off-label use or other promotional activity for opioids.

348. Plaintiffs are informed and believe, and thereupon allege, that the directors and CEO, including the Sacklers, also managed Purdue's focus on encouraging patients to use higher and higher doses of opioids, leading to health issues, addiction, and greater profits for the company. Upon learning that sales of 40mg and 80mg strengths of OxyContin had fallen below sales targets, the board received multiple reports that public health authority initiatives to have doctors consult with pain specialists before prescribing high opioid doses were a "threat." The

board oversaw measures to counteract against these initiatives and received reports in 2013 that attempts to encourage increased total daily doses had had a positive impact on the company's bottom line.

349. Plaintiffs are informed and believe, and thereupon allege, that the directors, including the Sacklers, additionally oversaw Purdue's plan to keep patients hooked on opioids for longer periods of time through higher doses. The board received thorough reports of how many patients remained on Purdue opioids for extended lengths of time, as well as internal documents that indicated patients on higher doses used the product for longer amounts of time, creating greater chances of addiction and abuse. The board was presented with a plan to create workshops, give specific direction to representatives about this link, and make increasing opioid use a focus point of the company. The board was told in writing that encouraging higher doses "is a focal point of our promotion" and that sales representatives should push doctors to increase patient doses as soon as three days after initial treatment. The board knew or should have known that this sales tactic was both deceptive and placing patients at high risk of addiction and overdose.

350. Plaintiffs are informed and believe, and thereupon allege, that the directors, including the Sacklers, also oversaw Purdue's targeting of prescribers without special knowledge of opioids, as they were the most likely to respond to Purdue's sales techniques. Purdue proceeded with this strategy despite the DEA expressing concern that Purdue was marketing its opioids to doctors who were not appropriately trained in pain management. The directors and CEO knew or should have known both that this strategy was deceptive and that targeting doctors who lacked special training in pain management and elderly patients increased the risk of addiction and overdose.

351. Plaintiffs are informed and believe, and thereupon allege, that Purdue's leadership, including the Sacklers, was also aware of a plan to steer patients away from safer pain-management medicines, which involved efforts to emphasize the danger of acetaminophen-based pain medication to the liver. These efforts included deceptive websites that the New York Attorney General specifically held to be misleading in specific sections.

352. Plaintiffs are informed and believe, and thereupon allege, that Purdue's leadership, including the Sacklers, also oversaw the response to thousands of harm reports from patients, in one case receiving over 5,000 complaints in a single quarter.

353. Plaintiffs are informed and believe, and thereupon allege, that Purdue possesses documents that show each of the reports mentioned above was sent to every individual defendant on the board, including every Sackler with a board position.

3. The Johnson & Johnson Defendants

354. Following a bench trial, on August 26, 2019, Judge Thad Balkman of the District Court of Cleveland County, Oklahoma entered judgement against Johnson & Johnson in *State of Oklahoma v. Purdue Pharma, L.P., et al*. for $572,000,000 (representing damages for a single year) to abate the public nuisance caused by its actions related to manufacturing and marketing opioids in the state of Oklahoma.[176] Judge Balkman found that "Defendants engaged in false and misleading marketing of both their drugs and opioids generally, and the law makes clear that such conduct is more than enough to serve as the act or omission necessary to establish the first element of Oklahoma's public nuisance law."

355. Johnson & Johnson is the only company that owns more than 10 percent of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products.

[176] *See* Judgement After Non-Jury Trial, *State of Oklahoma v. Purdue Pharma, et al*., No. CJ-2017-816 (Okla. Dist. Ct. Aug. 26, 2019) (hereinafter "Johnson & Johnson Judgement").

Upon information and belief, Johnson & Johnson controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to Johnson & Johnson's benefit. Together, Johnson & Johnson and Janssen (the "Johnson & Johnson Defendants"): (1) funded the production and dissemination of and disseminated false, misleading, and deceptive information about the efficacy and addictive properties of prescription opioids; and (2) failed to monitor and report suspicious sales as required by federal law.

356. As part of its "pain management franchise," from the 1990s through at least 2016, Johnson & Johnson wholly owned Tasmania Alkaloids Limited ("Tasmanian Alkaloids"), which was based in Tasmania and cultivated and processed opium poppy plants to manufacture narcotic raw materials to be imported into the U.S. to be processed and made into active pharmaceutical ingredients (APIs) necessary to manufacture opioid drugs. It also wholly owned Noramco, Inc. which is based in Athens, Georgia and imported the raw narcotic materials produced by Tasmania Alkaloids, processed the materials into APIs, then sold the APIs to other opioid manufacturers in the U.S.[177]

a) Janssen

357. Janssen manufactures, markets, sells, and distributes the following opioids in nationwide:

Duragesic (fentanyl)	Opioid analgesic delivered via skin patch; contains gel form of fentanyl, a synthetic opioid that is up to 100 times more potent than morphine; delivers fentanyl at regulated rate for up to 72 hours; first approved by the FDA in August 1990.	Schedule II
Nucynta ER (tapentadol hydrochloride)	Opioid agonist; extended-release formulation indicated for severe pain.	Schedule II
Nucynta (tapentadol hydrochloride)	Immediate-release version of tapentadol hydrochloride for the management of moderate to severe acute pain.	Schedule II

[177] Johnson & Johnson Judgement ¶ 6.

358. Janssen introduced Duragesic in 1990. It is indicated for the "management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Janssen also marketed Nucynta, which was first approved by the FDA in 2008, formulated in tablet form and in an oral solution and indicated for the "relief of moderate to severe acute pain in patients 18 years of age or older." Additionally, Janssen marketed Nucynta ER, which was first approved by the FDA in 2011 in tablet form. Initially, it was indicated for the "management of . . . pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." This pain indication was later altered to "management of moderate to severe chronic pain in adults" and "neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults." Janssen sold Nucynta and Nucynta ER to Depomed in 2015 for $1.05 billion.

359. In 1997, after seeing the success that Purdue had in marketing OxyContin for chronic non-cancer pain, the J&J Defendants re-launched their fentanyl-based Duragesic patch for the chronic, non-cancer market as well.

b) The FDA Warned Janssen Regarding Its False Messaging.

360. On February 15, 2000, the FDA sent Janssen a letter concerning the alleged dissemination of "homemade" promotional pieces that promoted Duragesic in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §301, *et seq.* In a subsequent letter, dated March 30, 2000, the FDA explained that the "homemade" promotional pieces were "false or misleading because they contain misrepresentations of safety information, broaden Duragesic's indication, contain unsubstantiated claims, and lack fair balance."

361. The March 30, 2000 letter identified specific violations, including misrepresentations that Duragesic had a low potential for abuse.[178]

362. The March 30, 2000 letter also stated that the promotional materials represented that Duragesic was "more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence." Specifically, the FDA stated that Janssen was marketing Duragesic for indications other than the treatment of chronic pain that cannot otherwise be managed, for which it was approved.[179]

363. The March 30, 2000 letter also stated Janssen failed to adequately present "contraindications, warnings, precautions, and side effects with a prominence and readability reasonably comparable to the presentation of information relating to the effectiveness of the product."[180]

364. On September 2, 2004, HHS sent Janssen a warning letter concerning Duragesic due to "false or misleading claims about the abuse potential and other risks of the drug, and . . . unsubstantiated effectiveness claims for Duragesic," including, specifically, "suggesting that Duragesic has a lower potential for abuse compared to other opioid products."

365. The September 2, 2004 letter warned Janssen regarding its claims that Duragesic had a low reported rate of mentions in the Drug Abuse Warning Network ("DAWN") as compared to other opioids. The letter stated that the claim was false or misleading because the

[178] NDA 19-813 Letter from Spencer Salis, U.S. Food & Drug Administration, to Cynthia Chianese, Janssen Pharmaceutical at 2 (Mar. 30, 2000), available at *County of Wayne and County of Oakland v. Purdue Pharma, et al*., No. 2:17-cv-13334-JCO-EAS, Dkt. 2-10 (E.D. Mich. Oct. 12, 2017).
[179] *Id*. at 2-3.
[180] *Id*. at 3 (emphasis in original).

claim was not based on substantial data and because the lower rate of mentions was likely attributable to Duragesic's lower frequency of use compared to other opioids listed in DAWN.[181]

366. The September 2, 2004 letter also detailed a series of unsubstantiated, false or misleading claims regarding Duragesic's effectiveness. The letter concluded that various claims made by Janssen were insufficiently supported, including:

- "Demonstrated effectiveness in chronic back pain with additional patient benefits, . . . 86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep."
- "All patients who experienced overall benefit from DURAGESIC would recommend it to others with chronic low back pain."
- "Significantly reduced nighttime awakenings."
- "Significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index."
- "Significant improvement in physical functioning summary score."
- "Significant improvement in social functioning."[182]

367. In addition, the September 2, 2004 letter identified "outcome claims [that] are misleading because they imply that patients will experience improved social or physical functioning or improved work productivity when using Duragesic." The claims include "'1,360 [lives] . . . and counting,' '[w]ork, uninterrupted,' '[l]ife, uninterrupted,' '[g]ame, uninterrupted,' '[c]hronic pain relief that supports functionality,' '[h]elps patients think less about their pain,' and '[i]mprove[s] . . . physical and social functioning.'" The September 2, 2004 letter stated:

[181] Warning Letter from Thomas W. Abrams, U.S. Department of Health and Human Services, to Ajit Shetty, Janssen Pharmaceutica, Inc., at 2 (Sept. 2, 2004), http://www.johnsonandtoxin.com/ 040920_duragesic_letter.pdf.
[182] *Id*. at 2-3.

"Janssen has not provided references to support these outcome claims. We are not aware of substantial evidence or substantial clinical experience to support these claims."[183]

368. On July 15, 2005, the FDA issued a public health advisory warning doctors of deaths resulting from the use of Duragesic and its generic competitor, manufactured by Mylan. The advisory noted that the FDA had been "examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch" and noted the possibility "that patients and physicians might be unaware of the risks" of using the fentanyl transdermal patch, which is a potent opioid analgesic meant to treat chronic pain that does not respond to other painkillers.

369. Regardless, even after receiving these letters, Janssen instructed sales representatives nationwide to market Duragesic as having better efficacy, better tolerability, and better patient compliance because it was a patch instead of a pill. These sales representatives were instructed to tell doctors that the patch provided better control in the event of patient opioid abuse because patients could not increase the patch dosage. However, sales representatives were aware of patients who increased the dosage by applying more than one patch at a time and were also aware that some patients abused the patch by freezing, then chewing on it.

c) The Johnson & Johnson Defendants Funded False Publications and Presentations.

370. Janssen disseminated false information about opioids on the website Prescribe Responsibly. According to the website's legal notice, all content on the site "is owned or controlled by Janssen."[184] The website includes numerous false or misleading representations

[183] *Id.* at 3.
[184] *Legal Notice*, Prescribe Responsibly, https://web.archive.org/web/20171003192940/http://www.prescriberesponsibly.com/legal-notice (last visited Sept. 19, 2019).

concerning the relative safety of opioids and omissions of the risks associated with taking them. For example, it states that while practitioners are often concerned about prescribing opioids due to "questions of addiction," such concerns "are often overestimated. According to clinical opinion polls, true addiction occurs only in a small percentage of patients with chronic pain who receive chronic opioid . . . analgesic therapy."[185]

371. Prescribe Responsibly also compared the risks of opioid use favorably to those associated with nonsteroidal anti-inflammatory drugs ("NSAIDs"), such as aspirin and ibuprofen, and stated that many patients develop tolerance for opioids' side effects: Opioid analgesics are often the first line of treatment for many painful conditions and may offer advantages over NSAIDs.

> Opioid analgesics, for example, have no true "ceiling dose" for analgesia and do not cause direct organ damage; however, they do have several possible side effects, including constipation, nausea, vomiting, a decrease in sexual interest, drowsiness, and respiratory depression. With the exception of constipation, many patients often develop tolerance to most of the opioid analgesic-related side effects.[186]

372. Further, Prescribe Responsibly repeats the scientifically unsupported discussion of "pseudoaddiction" as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases."[187] Thus, "pseudoaddiction" is defined as a condition requiring the prescription of more or stronger opioids.

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[185] *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, https://web.archive.org/web/20180714193514/http://www.prescriberesponsibly.com/articles/opioid-pain-management (last visited Sept. 19, 2019).
[186] *Id.*
[187] *What a Prescriber Should Know Before Writing the First Prescription*, Prescribe Responsibly, https://web.archive.org/web/20180720092635/http://www.prescriberesponsibly.com/articles/before-prescribing-opioids (last visited Sept. 19, 2019).

373. Another unbranded marketing initiative that Johnson & Johnson Defendants employed was the dissemination of a brochure, titled "Finding Relief," which was sponsored by AAPM.[188] The Finding Relief brochure, which was widely disseminated, did not differentiate between different kinds of opioids and discussed them as a class of drugs without reference to any of the differences between them. The Finding Relief brochure actively promoted the concept that pain was undertreated. The brochure downplayed any risks associated with opioids.[189]

374. Janssen also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services.

375. The Oklahoma trial court found that Johnson & Johnson Defendants used a sales force to promote, market, and sell various types of opioids, including branded opioid drugs that Johnson & Johnson and its subsidiary Janssen themselves manufactured: Duragesic, Ultram, and Nucynta.[190]

376. The Johnson & Johnson Defendants training of its sales representatives included teaching sales representatives to avoid the so-called "addiction ditch"—i.e. to avoid the negatives (addiction) and emphasize the positives (supposed efficacy) in sales calls—and to use a study from Dr. Portenoy "to create dialogue about Opiophobia as a barrier."[191]

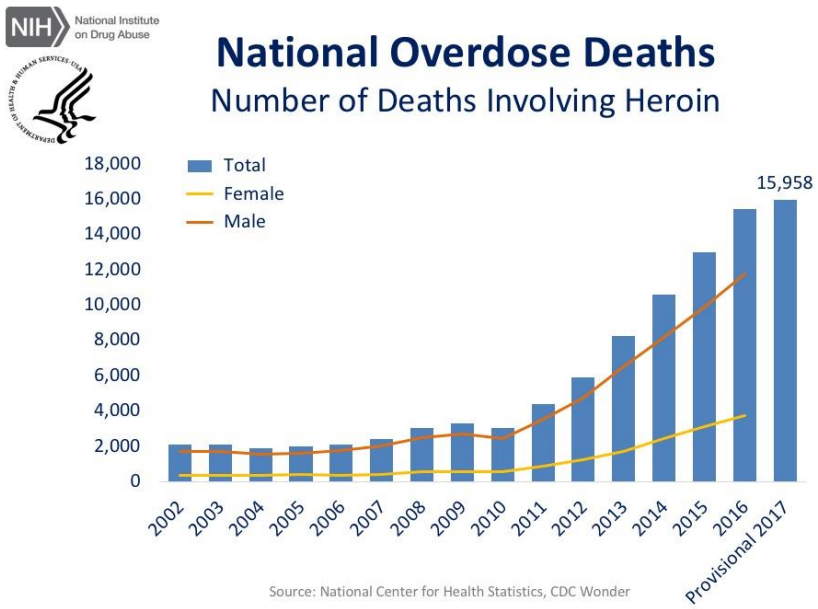
377. As part of this training, the Johnson & Johnson trained their sales representatives that there was a 2.6% or lower risk of addiction when using opioids prescribed by a doctor. As

[188] Finding Relief: Pain Management for Older Adults (2009), available at https://docplayer.net/28610911-Finding-relief-pain-management-for-older-adults.html (last visited Sept. 27, 2019).
[189] Johnson & Johnson Judgement ¶ 24.
[190] *Id.* at ¶¶ 26-29.
[191] *Id*. at ¶ 27.

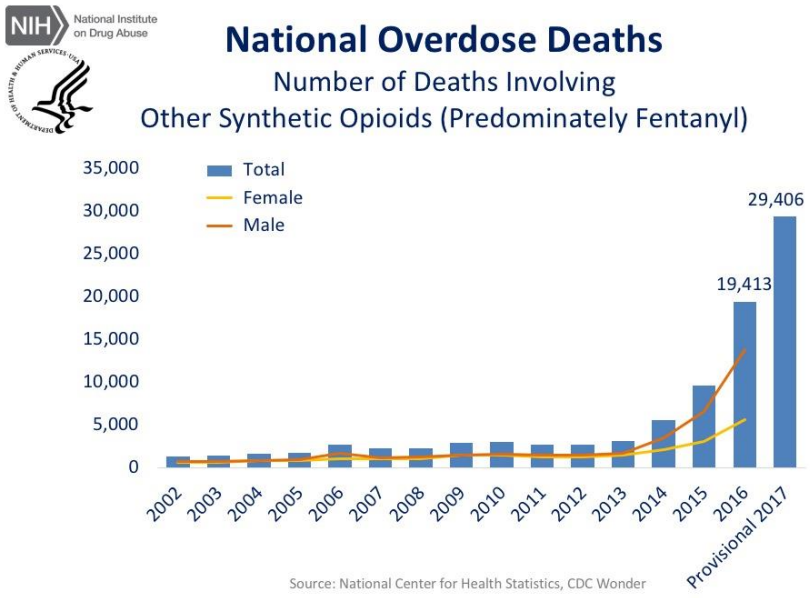
part of this same training, Johnson & Johnson and Janssen trained sales representatives to "establish that moderate to severe acute pain continues to be undertreated."[192]

378. The Oklahoma trial court found that Johnson & Johnson and Janssen did not provide its sales force with any training on opioid addiction.

379. As people became more and more hooked on prescription painkillers, many moved to heroin, and increasingly to fentanyl, which is even more potent and cheaper than heroin, and is increasingly mixed with or sold as heroin and, as set forth above, was also being deceptively marketed by Janssen. This transition to heroin and fentanyl caused a dramatic spike in heroin overdose deaths after 2011 and in fentanyl overdose deaths in 2014:



[192] *Id.* at ¶ 28.



d) The Johnson & Johnson Defendants Failed to Monitor and Report Suspicious Sales as Required by Federal Law.

380. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

381. The Johnson & Johnson Defendants are "registrants" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

382. The Johnson & Johnson Defendants failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. They also failed to report to the Board sales of dangerous

drugs subject to abuse. Their failure to timely report these and other suspicious sales violated the CSA.

e) In addition to marketing its own opioids, Johnson & Johnson owned two companies that grew, imported, and processed the raw materials to make opioids and sold them to many of the other Manufacturing Defendants, including Purdue.

383. Until 2016, when Johnson & Johnson sold its Noramco/Tasmanian Alkaloids business, Tasmanian Alkaloids and Noramco were "sister companies," as "both of them were" members of Defendants' "family of companies." Noramco employees did not believe Noramco maintained its own bank accounts, separate from Johnson & Johnson's treasury. Johnson & Johnson, Noramco, and Tasmanian Alkaloids shared employees and resources that were required to operate the business. Noramco employees physically worked at Johnson & Johnson's facilities in New Jersey at various times. Further, employees simultaneously held positions at multiple companies within the Johnson & Johnson Family of Companies at times. During this time, Noramco and Tasmanian Alkaloids were key parts of Johnson & Johnson's "pain management franchise" or "pain franchise."[193]

384. Johnson & Johnson, through these subsidiaries, supplied the following opioid active pharmaceutical ingredients ("API") to other drug manufacturers in the U.S., including Purdue and Teva: oxycodone, hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone.[194]

385. In the 1980s, Johnson & Johnson acquired and formed Tasmanian Alkaloids and Noramco, in order to ensure a "reliable source of [narcotic] raw materials" and "security of supply" for its Tylenol with Codeine range of pain medications.[195]

[193] Johnson & Johnson Judgement ¶ 7.
[194] *Id*. at ¶ 8.
[195] *Id*. at ¶ 9.

386. Noramco, located in the U.S., imports the narcotic raw materials produced by Tasmanian Alkaloids, like morphine or thebaine,[196] into the U.S., processes them into APIs, then sells them to drug manufacturers in the U.S. Noramco was "an important part of J&J's business" from the mid-1990s until at least 2010. Johnson & Johnson's ownership of these subsidiaries uniquely positioned its pain management franchise to provide U.S. drug manufacturers, including Johnson & Johnson itself, with "Security of Supply-Direct Access to Narcotic Raw Material - From Our Fields to Your Formulations." Through its subsidiary, Noramco, Johnson & Johnson supplied oxycodone API to other drug manufacturers.[197]

387. In 1994, Johnson & Johnson, in concert with its subsidiary, Tasmanian Alkaloids, anticipated demand for oxycodone. Specifically, Johnson & Johnson scientists at Tasmanian Alkaloids began a project "in 1994 in order to develop a high thebaine poppy variety to meet the anticipated demand." The result of Defendants' research project was the creation of a "high thebaine" poppy called the "Norman Poppy," which Johnson & Johnson internally described as "a transformational technology that enabled the growth of oxycodone."[198]

388. Through Noramco, Johnson & Johnson met the anticipated opioid demand by selling API, including oxycodone, to Purdue.[199]

389. Through Noramco, Defendants supplied API to other opioid manufacturers, including Teva. Noramco sold the majority of its controlled substance via long-term agreements and had such agreements with all 7 of the top U.S. generic companies. Through Noramco,

[196] Thebaine is an opiate alkaloid, chemically similar to morphine and codeine, used as an intermediate in the biosynthesis of other opioids.
[197] *Id.* at ¶ 10.
[198] *Id.* at ¶ 11.
[199] *Id.* at ¶ 12.

Defendants supplied other U.S. opioid manufacturers with opioid APIs, including: oxycodone, hydrocodone, morphine, codeine, buprenorphine, hydromorphone, and naloxone.[200]

390. Noramco grew to become the number one narcotic API supplier of oxycodone, hydrocodone, codeine and morphine in the United States.[201]

4. Endo

391. Endo manufactures, markets, sells, and distributes the following opioids nationwide:

Opana ER (oxymorphone hydrochloride)	Opioid agonist; extended-release tablet formulation; first drug in which oxymorphone was available in an oral, extended-release formulation; first approved in 2006.	Schedule II
Opana (oxymorphone hydrochloride)	Opioid agonist; first approved in 2006.	Schedule II
Percodan (oxymorphone hydrochloride and aspirin)	Branded tablet combining oxymorphone hydrochloride and aspirin; first approved in 1950; first marketed by Endo in 2004.	Schedule II
Percocet (oxymorphone hydrochloride and acetaminophen)	Branded tablet that combines oxymorphone hydrochloride and acetaminophen; first approved in 1999; first marketed by Endo in 2006.	Schedule II
Oxycodone	Generic product.	Schedule II
Oxymorphone	Generic product.	Schedule II
Hydromorphone	Generic product.	Schedule II
Hydrocodone	Generic product.	Schedule II

392. The FDA first approved an injectable form of Opana in 1959. The injectable form of Opana was indicated "for the relief of moderate to severe pain" and "for preoperative medication, for support of anesthesia, for obstetrical analgesia, and for relief of anxiety in patients with dyspnea associated with pulmonary edema secondary to acute left ventricular

[200] *Id*. at ¶ 14.
[201] *Id*. at ¶ 15.

dysfunction." However, oxymorphone drugs were removed from the market in the 1970s due to widespread abuse.[202]

393. In 2006, the FDA approved a tablet form of Opana in 5 mg and 10 mg strengths. The tablet form was "indicated for the relief of moderate to severe acute pain where the use of an opioid is appropriate." Also in 2006, the FDA approved Opana ER, an extended-release tablet version of Opana available in 5 mg, 10 mg, 20 mg, and 40 mg tablet strengths. Opana ER was indicated "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Endo's goal was to use Opana ER to take market share away from OxyContin; thus, it was marketed as being safer, with less abuse potential than OxyContin because it is supposed to be crush-resistant.

394. According to Endo's annual reports, sales of Opana and Opana ER regularly generate several hundred million dollars in annual revenue for the company, growing from $107 million in 2007 to as high as $384 million in 2011. Over the last ten years, Percocet has generated an average of well over $100 million in annual revenue for the company.

a) Endo Falsely Marketed Opana ER as Crush Resistant.

395. In December 2011, the FDA approved a reformulated version of Opana ER, which Endo claimed offered "safety advantages" over the original formulation because the new version "is resistant to crushing by common methods and tools employed by abusers of prescription opioids . . . [and] is less likely to be chewed or crushed even in situations where there is no intent for abuse, such as where patients inadvertently chew the tablets, or where

[202] John Fauber & Kristina Fiore, *Opana gets FDA approval despite history of abuse, limited effectiveness in trials*, Milwaukee Journal Sentinel (May 9, 2015), http://archive.jsonline.com/watchdog/watchdogreports/opana-gets-fda-approval-despite-history-of-abuse-limited-effectiveness-intrials-b99494132z1-303198321.html/.

caregivers attempt to crush the tablets for easier administration with food or by gastric tubes, or where children accidentally gain access to the tablets."

396. Endo publicized the reformulated version of Opana ER as "crush-resistant." To combat the fear of opioids, sales representatives touted it to doctors as a safer option due to its crush-resistance and extended release.

397. However, in October 2012, the CDC issued a health alert noting that 15 people in Tennessee had contracted thrombotic thrombocytopenic purpura, a rare blood-clotting disorder, after injecting reformulated Opana ER. In response, Endo's chief scientific officer stated that, while Endo was looking into the data, he was not especially concerned because "it's in a very, very distinct area of the country."[203]

398. Shortly thereafter, the FDA determined that Endo's conclusions about the purported safety advantages of the reformulated Opana ER were unfounded. In a May 10, 2013 letter to Endo, the FDA found that the tablet was still vulnerable to "cutting, grinding, or chewing," "can be prepared for insufflation (snorting) using commonly available tools and methods" and "can [be readily] prepared for injection." It also warned that preliminary data suggested "the troubling possibility that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation."

399. A 2014 study co-authored by an Endo medical director corroborated the FDA's warning. This 2014 study found that while overall abuse of Opana had fallen following Opana ER's reformulation, injection had become the preferred way of abusing the drug.[204] However,

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[203] Tom Dreisbach et al., *How A Painkiller Designed To Deter Abuse Helped Spark An HIV Outbreak*, National Public Radio (Apr. 1, 2016), http://www.npr.org/sections/healthshots/2016/04/01/472538272/how-a-painkiller-designed-to-deter-abuse-helped-spark-an-hiv-outbreak.

[204] *Id.*

and incredibly, the study reassured that it was not possible to draw a causal link between the reformulation and injection abuse.

400. The study's failure to adequately warn healthcare providers and the public was catastrophic. On April 24, 2015, the CDC issued a health advisory concerning its investigation of "a large outbreak of recent human immunodeficiency virus (HIV) infections among persons who inject drugs."[205] The CDC specifically attributed the outbreak to the injection of Opana ER.[206]

b) New York's Investigation Found Endo Falsely Marketed Opana ER.

401. On February 18, 2017, the State of New York announced a settlement with Endo requiring it "to cease all misrepresentations regarding the properties of Opana ER [and] to describe accurately the risk of addiction to Opana ER."[207] In the Assurance of Discontinuance that effectuated the settlement, the State of New York revealed evidence showing that Endo had known about the risks arising from the reformulated Opana ER even before it received FDA approval.

402. In October 2011, one month before the FDA's approval of reformulated Opana ER, Endo's director of project management e-mailed the company that developed the formulation technology for the drug to say there was little or no difference between the new formulation and the earlier formulation, which Endo withdrew due to risks associated with grinding and chewing:

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[205] *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs*, Centers for Disease Control and Prevention, https://emergency.cdc.gov/han/han00377.asp (last visited Sept. 26, 2019).
[206] *Id.*
[207] Press Release, Attorney General Eric T. Schneiderman, A.G. Schneiderman Announces Settlement With Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing Of Prescription Opioid Drugs (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneidermanannounces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

> "*We already demonstrated that there was little difference between [the original and new formulations of Opana] in Study 108 when both products were ground. FDA deemed that there was no difference* and this contributed to their statement that we had not shown an incremental benefit. *The chewing study (109) showed the same thing no real difference* which the FDA used to claim no incremental benefit."[208]

403. Endo conducted two additional studies to test the reformulated Opana ER's crush resistance. Study 901 tested whether it was more difficult to extract opioid from reformulated Opana ER than from the original version, and whether it would take longer to extract opioid from reformulated Opana ER than from the original version. The test revealed that both formulations behaved similarly with respect to manipulation time and produced equivalent opioid yields.

404. The settlement also identified and discussed a February 2013 communication from a consultant hired by Endo to the company, in which the consultant concluded that "[t]he initial data presented do not necessarily establish that the reformulated Opana ER is tamper resistant." The same consultant also reported that the distribution of the reformulated Opana ER had already led to higher levels of abuse of the drug via injection.[209]

405. Despite the results of Endo's own studies and the conclusions of both Endo's director of project management and consultant, pamphlets produced by Endo and distributed to physicians misleadingly marketed the reformulated Opana ER as "'designed to be' crush resistant," and Endo's sales representative training identified Opana ER as "CR," short for crush resistant.[210]

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[208] *In the Matter of Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.*, Assurance No. 15-228, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5 (Mar. 1, 2016), (hereinafter "NYAG Endo Discontinuance") https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.
[209] *Id.*
[210] *Id.*

406. The Office of the Attorney General of New York also revealed that the "managed care dossier" Endo provided to formulary[211] committees of healthcare plans and PBMs misrepresented the Opana ER studies. The dossier was distributed in order to assure the inclusion of reformulated Opana ER in their formularies.

407. According to Endo's Vice President for Pharmacovigilance and Risk Management, the dossier was presented as a complete compendium of all research on the drug. However, it omitted certain studies: Study 108 (completed in 2009) and Study 109 (completed in 2010), which showed that reformulated Opana ER could be ground and chewed.

408. The settlement also detailed Endo's false and misleading representations about the non-addictiveness of opioids and Opana. Until April 2012, Endo's website for the drug, www.opana.com, contained the following representation: "Most healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted."[212] However, Endo neither conducted nor possessed a survey demonstrating that most healthcare providers who treat patients with pain agree with that representation.

409. The Office of the Attorney General of New York also disclosed that training materials provided by Endo to sales representatives stated: "Symptoms of withdrawal do not indicate addiction."[213] This representation is inconsistent with the diagnosis of opioid-use disorder as provided in the *Diagnostic and Statistical Manual of Mental Disorders by the American Psychiatric Association (Fifth Edition)*.

410. The Office of the Attorney General of New York also found that Endo trained its sales representatives to falsely distinguish addiction from "pseudoaddiction," which it defined as

[211] A formulary is the official list of medicines that may be prescribed in a particular health care plan.
[212] NYAG Endo Discontinuance, *supra* n. 208.
[213] *Id*. at 7.

a condition in which patients exhibit drug-seeking behavior that resembles, but is not the same as, addiction. However, Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the concept of pseudoaddiction.

c) Endo Funded False Publications and Presentations.

411. Like several of the other Manufacturing Defendants, Endo provided substantial funding to purportedly neutral medical organizations, including the APF.

412. For example, in April 2007, Endo sponsored an article aimed at prescribers, written by Dr. Charles E. Argoff in *Pain Medicine News*, titled, "Case Challenges in Pain Management: Opioid Therapy for Chronic Pain."[214]

413. The article commenced with the observation that "[a]n estimated 50 to 60 million people . . . suffer from chronic pain." It continued:

> Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.[215]

414. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids. It concluded by saying that "use of opioids may be effective in the management of chronic pain."

[214] Charles E. Argoff, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain*, Pain Med. News, http://www.painmedicinenews.com/download/BtoB_Opana_WM.pdf.
[215] *Id*.

415. Later, in 2014, Endo issued a patient brochure titled, "Understanding Your Pain: Taking Oral Opioid Analgesics." It was written by nurses Margo McCaffery and Chris Pasero and edited by APF board member Portenoy.

416. The brochure included numerous false and misleading statements minimizing the dangers associated with prescription opioid use. Among other things, the brochure falsely and misleadingly represented that:

> Addiction **IS NOT** when a person develops "withdrawal" (such as abdominal cramping or sweating) after the medicine is stopped quickly or the dose is reduced by a large amount. Your doctor will avoid stopping your medication suddenly by slowly reducing the amount of opioid you take before the medicine is completely stopped. Addiction also **IS NOT** what happens when some people taking opioids need to take a higher dose after a period of time in order for it to continue to relieve their pain. This normal "tolerance" to opioid medications doesn't affect everyone who takes them and does not, by itself, imply addiction. If tolerance does occur, it does not mean you will "run out" of pain relief. Your dose can be adjusted or another medicine can be prescribed.
>
> * * *
>
> *How can I be sure I'm not addicted?*
>
> - Addiction to an opioid would mean that your pain has gone away but you still take the medicine regularly when you don't need it for pain, maybe just to escape from your problems.
>
> - Ask yourself: Would I want to take this medicine if my pain went away? If you answer no, you are taking opioids for the right reasons – to relieve your pain and improve your function. You are not addicted.[216]
>
> * * *

417. In 2008, Endo also provided an "educational grant" to PainEDU.org, which produced a document titled, "Screener and Opioid Assessment for Patients with Pain (SOAPP)

[216] Margo McCaffrey et al., *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

Version 1.0-14Q." Endo and King Pharmaceuticals sponsor PainEDU.org.[217] SOAPP describes itself "as a tool for clinicians to help determine how much monitoring a patient on long-term opioid therapy might require." It falsely highlights purportedly "recent findings suggesting that most patients are able to successfully remain on long-term opioid therapy without significant problems."

418. Endo also sponsored the now-defunct website painknowledge.com, which was created by the APF and stated it was "a one-stop repository for print materials, educational resources, and physician tools across the broad spectrum of pain assessment, treatment, and management approaches."[218] Among other featured content, painknowledge.com included a flyer titled, "Pain: Opioid Therapy," which failed to warn of significant adverse effects that could arise from opioid use, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, decreased tolerance, dependence and addiction.

419. Endo, along with Janssen and Purdue, also provided grants to the APF to distribute Exit Wounds, discussed above. *See supra* ¶ 188.

420. Endo also made thousands of payments to physicians nationwide for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance, and other services.

d) The FDA Requested Endo Withdraw Opana ER Due to the Public Health Consequences of Abuse.

421. On June 8, 2017, the FDA requested that Endo remove reformulated Opana ER from the market "based on its concern that the benefits of the drug may no longer outweigh its

[217] B. Eliot Cole, *Resources for Education on Pain and Its Management: A Practitioner's Compendium* 2 (Am. Society of Pain Educators 2009), https://www.nhms.org/sites/default/files/Pdfs/SOAPP-5.pdf.
[218] *AboutPainKnowledge.org*, PainKnowledge, http://web.archive.org/web/20120119124921/http://www.painknowledge.org/aboutpaink.aspx (last visited Dec. 14, 2018).

risks." According to the FDA's press release, it sought removal "due to the public health consequences of abuse." The decision to seek Opana ER's removal from sale followed a March 2017 FDA advisory committee meeting, during which a group of independent experts voted 18-8 that the drug's benefits no longer outweigh the risks associated with its use. According to Dr. Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, the risks include "several serious problems," including "outbreaks of HIV and Hepatitis C from sharing the drug after it was extracted by abusers" and "a[n] outbreak of serious blood disorder." Dr. Woodcock stated that if Endo did not comply with the request, the FDA would issue a notice of a hearing and commence proceedings to compel its removal from the market.

422. On July 6, 2017, Endo pulled Opana ER from the U.S. market.

e) Endo Failed to Monitor and Report Suspicious Sales as Required.

423. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

424. Endo is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

425. Endo failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Endo also failed to report to the Board sales of suspicious drugs subject to abuse. Endo's failure to timely report these and other suspicious sales violated the CSA.

5. Cephalon

426. Cephalon manufactures, markets, sells and distributes the following opioids nationwide:

Actiq (fentanyl citrate)	Opioid analgesic; oral transmucosal lozenge; indicated only for the management of breakthrough pain ("BTP") in cancer patients – pain that for a short time "breaks through" medication that otherwise effectively controls a patient's persistent pain – in patients 16 and older with malignancies; commonly referred to as a lollipop because designed to look and perform like one; approved in 1998 with restricted distribution program.	Schedule II
Fentora (fentanyl buccal)	Rapid-release tablet for BTP in cancer patients who are already receiving and tolerant of around-the-clock opioid therapy; approved in 2006.	Schedule II
Generic of OxyContin (oxycodone hydrochloride)	Opiate agonist.	Schedule II

427. Actiq is designed to resemble a lollipop and is meant to be sucked on at the onset of intense breakthrough pain ("BTP")[219] in cancer patients. It delivers fentanyl citrate, a powerful opioid agonist that is 80 times stronger than morphine,[220] rapidly into a patient's bloodstream through the oral membranes.[221] Because it is absorbed through those membranes, it passes directly into circulation without having to go through the liver or stomach, thereby providing faster relief.[222]

[219] Breakthrough pain, or BTP, is an intense spike of pain experienced by some cancer patients when the pain exceeds the level which is controlled by chronic pain medications.
[220] *See* John Carreyrou, *Narcotic "Lollipop" Becomes Big Seller Despite FDA Curbs*, Wall St. J. (Nov. 3, 2006), https://www.wsj.com/articles/SB116252463810112292 (hereinafter, "Carreyrou, *Narcotic Lollipop*").
[221] Actiq would later become part of a category of opioids now known as transmucosal immediate-release fentanyl ("TIRF") products. "Transmucosal" refers to the means through which the opioid is delivered into a patient's bloodstream, across mucous membranes, such as inside the cheek, under the tongue, or in the nose.
[222] *Cephalon, Inc.*, Company-Histories.com, http://www.companyhistories.com/Cephalon-Inc-Company-History.html (last visited Dec. 14, 2018).

428. In November 1998, the FDA approved Actiq for only a very narrow group of people – cancer patients "with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[223]

429. Understanding the risks of introducing such an intense opioid analgesic to the market, the FDA provided approval of Actiq "*ONLY* for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."[224] Further, the FDA explicitly stated that Actiq "*must not* be used in opioid non-tolerant patients," was contraindicated for the management of acute or postoperative pain, could be deadly to children and was "intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain."

430. The FDA also required that Actiq be provided only in compliance with a strict risk management program that explicitly limited the drug's direct marketing to the approved target audiences, defined as oncologists, pain specialists, their nurses and office staff.[225]

431. In October 2000, Cephalon acquired the worldwide product rights to Actiq and began marketing and selling Actiq in the United States.

432. Cephalon also purchased the rights to Fentora, an even faster-acting tablet formulation of fentanyl, from Cima Labs, and submitted a new drug application to the FDA in August 2005. In September 2006, Cephalon received FDA approval to sell Fentora as a faster-

[223] 1998 FDA Label, https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/20747_Actiq_appltr.pdf.
[224] NDA 20-747 Letter from Cynthia McCormick, Center for Drug Evaluation and Research, to Patricia J. Richards, Anesta Corporation, http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20747ltr.pdf.
[225] Carreyrou, *Narcotic Lollipop*, *supra* n.220.

acting version of Actiq; but once again concerned about the power and risks inherent to fentanyl, the FDA limited Fentora's approval to the treatment of BTP in cancer patients who were already tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Cephalon began marketing and selling Fentora in October 2006.

a) Cephalon Falsely and Aggressively Marketed Cancer Drug Actiq to Non-Cancer Treating Physicians.

433. Due to the FDA's restrictions, Actiq's consumer base was limited, as was its potential for revenue growth. In order to increase its revenue and market share, Cephalon needed to find a broader audience for the drug, and thus began marketing its opioid lollipop to treat headaches, back pain, sports injuries, and other chronic non-cancer pain. Cephalon targeted non-oncology practices, including, but not limited to, pain doctors, general practitioners, migraine clinics, anesthesiologists, and sports clinics. It did so in violation of applicable regulations prohibiting the marketing of medications for off-label use and in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

434. According to "[d]ata gathered from a network of doctors by research firm ImpactRx between June 2005 and October 2006" ("ImpactRx Survey"), Cephalon sales representatives' visits to non-oncologists to market Actiq increased six-fold between 2002 and 2005. Cephalon representatives would reportedly visit non-oncologists monthly, providing up to 60 or 70 coupons (each coupon was good for six free Actiq lozenges) and encouraging prescribers to try Actiq on their non-cancer patients.[226]

[226] *Id.*

435. Cephalon's efforts paid off. In 2000, Actiq generated $15 million in sales.[227] By 2002, it attributed a 92% increase in Actiq sales to "a dedicated sales force for ACTIQ" and "ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists."[228] By 2005, Actiq's sales total had jumped to $412 million, making it Cephalon's second-best-selling drug. By the end of 2006, Actiq's sales had exceeded $500 million.

436. Although Actiq is a drug approved for only a very narrow customer base, during the first six months of 2006, only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies were prescribed by oncologists. Results of the ImpactRx Survey suggested that "more than 80 percent of patients who use[d] the drug don't have cancer."[229]

b) Government Investigations Found Cephalon Falsely Marketed Actiq for Off-Label Uses.

437. Beginning in or about 2003, former Cephalon employees filed four whistleblower lawsuits claiming the company had wrongfully marketed Actiq for unapproved, off-label uses. On September 29, 2008, Cephalon finalized and entered into a corporate integrity agreement with the Office of the Inspector General of HHS and agreed to pay $425 million in civil and criminal penalties for its off-label marketing of Actiq and two other drugs (Gabitril and Provigil). According to a DOJ press release, Cephalon trained sales representatives to disregard restrictions of the FDA-approved label, employed sales representatives and healthcare professionals to speak

[227] *Id.*
[228] Cephalon, Inc. Annual Report (Form 10-K) at 28 (Mar. 31, 2003), http://getfilings.com/o0001047469-03-011137.html.
[229] Carreyrou, *Narcotic Lollipop*, *supra* n.220.

to physicians about off-label uses of the three drugs, and funded CME to promote off-label uses.[230]

438. Upon information and belief, documents uncovered in the government's investigations confirm that Cephalon directly targeted non-oncology practices and pushed its sales representatives to market Actiq for off-label use. For instance, the government's investigations confirmed:

- Cephalon instructed its sales representatives to ask non-cancer doctors whether they have the potential to treat cancer pain. Even if the doctor answered "no," a decision tree provided by Cephalon instructed the sales representatives to give these physicians free Actiq coupons.
- Cephalon targeted neurologists in order to encourage them to prescribe Actiq to patients with migraine headaches.
- Cephalon sales representatives utilized the assistance of outside pain management specialists when visiting non-cancer physicians to pitch Actiq. The pain management specialist would falsely inform the physician that Actiq does not cause patients to experience a "high" and carries a low risk of diversion toward recreational use.
- Cephalon set sales quotas for its sales and marketing representatives that could not possibly have been met solely by promoting Actiq for its FDA-approved indication.
- Cephalon promoted the use of higher doses of Actiq than patients required by encouraging prescriptions of the drug to include larger-than-necessary numbers of lozenges with unnecessarily high doses of fentanyl.
- Cephalon promoted Actiq for off-label use by funding and controlling CME seminars that promoted and misrepresented the efficacy of the drug for off-label uses such as treating migraine headaches and for patients not already opioid tolerant.[231]

[230] Press Release, U.S. Department of Justice, Pharmaceutical Company Cephalon To Pay $425 Million For Off-Label Drug Marketing (Sept. 29, 2008), https://www.justice.gov/archive/usao/pae/News/2008/sep/cephalonrelease.pdf.
[231] John Carreyrou, *Cephalon Used Improper Tactics to Sell Drug, Probe Finds*, Wall St. J. Nov. 21, 2006, at B1 (hereinafter, "Carreyrou, *Cephalon Used Improper Tactics*").

439. Still, the letters, the FDA's safety alert, the government's investigations, and the massive settlement seemed to have had little impact on Cephalon as it continued its deceptive marketing strategy for both Actiq and Fentora.

c) Cephalon Falsely and Aggressively Marketed Cancer Drug Fentora to Non-Cancer Treating Physicians.

440. From the time it first introduced Fentora to the market in October 2006, Cephalon targeted non-cancer doctors; falsely represented Fentora as a safe, effective off-label treatment for noncancer pain; and continued its disinformation campaign about the safety and non-addictiveness of Fentora specifically and opioids generally. In fact, Cephalon targeted the same pain specialists and non-oncologists that it had targeted with its off-label marketing of Actiq, simply substituting Fentora.

441. During an investor earnings call shortly after Fentora's launch, Cephalon's CEO described the "opportunity" presented by the use of Fentora for non-cancer pain:

> *The other opportunity of course is the prospect for FENTORA outside of cancer pain, in indications such as breakthrough lower back pain and breakthrough neuropathic pain*.

* * *

> Of all the patients taking chronic opioids, 32% of them take that medication to treat back pain, and 30% of them are taking their opioids to treat neuropathic pain. In contrast only 12% are taking them to treat cancer pain, 12%.
>
> We know from our own studies that breakthrough pain episodes experienced by these non-cancer sufferers respond very well to FENTORA. And for all these reasons, we are tremendously excited about the significant impact FENTORA can have on patient health and well-being and the exciting growth potential that it has for Cephalon.
>
> In summary, we have had a strong launch of FENTORA and continue to grow the product aggressively. Today, that growth is coming from the physicians and patient types that we have identified through our efforts in the field over the last

> seven years. In the future, with new and broader indications and a much bigger field force presence, the opportunity that FENTORA represents is enormous.[232]

d) The FDA Warned Cephalon Regarding its False and Off-Label Marketing of Fentora.

442. On September 27, 2007, the FDA issued a public health advisory to address numerous reports that patients who did not have cancer or were not opioid tolerant had been prescribed Fentora and warned of death or life-threatening side effects. The FDA warned: Fentora should not be used to treat any type of short-term pain such as headaches or migraines, and that it should only be used under the close supervision of a doctor.[233]

443. Nevertheless, in 2008, Cephalon pushed forward to expand the target base for Fentora and filed a supplemental drug application requesting FDA approval of Fentora for the treatment of noncancer BTP. In the application and supporting presentations to the FDA, Cephalon admitted both that it knew the drug was heavily prescribed for off-label use and that the drug's safety for such use had never been clinically evaluated.[234] An FDA advisory committee lamented that Fentora's existing risk management program was ineffective and stated that Cephalon would have to institute a risk evaluation and mitigation strategy for the drug before the FDA would consider broader label indications. In response, Cephalon revised Fentora's label and medication guide to add strengthened warnings.

444. But in 2009, the FDA once again informed Cephalon that the risk management program was not sufficient to ensure the safe use of Fentora for already approved indications.

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[232] Seeking Alpha, Transcript of Q1 2007 Cephalon, Inc. Earnings Conference Call (May 1, 2007), http://seekingalpha.com/article/34163-cephalon-q1-2007-earnings-call-transcript.
[233] FDA safety page: How to use Fentora safely, Drug Topics, https://www.drugtopics.com/fda/fda-safety-page-how-use-fentora-safely (last accessed Sept. 25, 2019).
[234] *FENTORA (fentanyl buccal tablet) CII, Joint Meeting of Anesthetic and Life Support Drugs and Drug Safety and Risk Management Advisory Committee*, U.S. Food & Drug Administration (May 6, 2008).

445. On March 26, 2009, the FDA warned Cephalon against its misleading advertising of Fentora ("Warning Letter"). The Warning Letter described a Fentora Internet advertisement as misleading because it purported to broaden "the indication for Fentora by implying that any patient with cancer who requires treatment for breakthrough pain is a candidate for Fentora . . . when this is not the case." Rather, Fentora was only indicated for those who were already opioid tolerant. It further criticized Cephalon's other direct Fentora advertisements because they did not disclose the risks associated with the drug.

446. Flagrantly disregarding the FDA's refusal to approve Fentora for non-cancer BTP and its warning against marketing the drug for the same, Cephalon continued to use the same sales tactics to push Fentora as it did with Actiq.

447. For example, on January 13, 2012, Cephalon published an insert in *Pharmacy Times* titled, "An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)." Despite the repeated warnings of the dangers associated with the use of the drugs beyond their limited indication, as detailed above, the first sentence of the insert stated: "It is well recognized that the judicious use of opioids can facilitate effective and safe management of chronic pain."[235]

e) Cephalon Funded False Publications and Presentations.

448. In addition to its direct marketing, Cephalon indirectly marketed through third parties to change the way doctors viewed and prescribed opioids – disseminating the unproven and deceptive messages that opioids were safe for the treatment of chronic, long-term pain; that they were nonaddictive; and that they were woefully under-prescribed to the detriment of

[235] *An Integrated Risk Evaluation and Mitigation Strategy (REMS) for FENTORA (Fentanyl Buccal Tablet) and ACTIQ (Oral Transmucosal Fentanyl Citrate)*, Pharmacy Times (Jan. 13, 2012), http://www.pharmacytimes.com/publications/issue/2012/january2012/r514-jan-12-rems.

patients who were needlessly suffering. It did so by sponsoring pro-opioid front groups, misleading prescription guidelines, articles, and CME programs, as well as by paying physicians thousands of dollars every year to publicly opine that opioids were safe, effective, and non-addictive for a wide variety of uses.

449. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

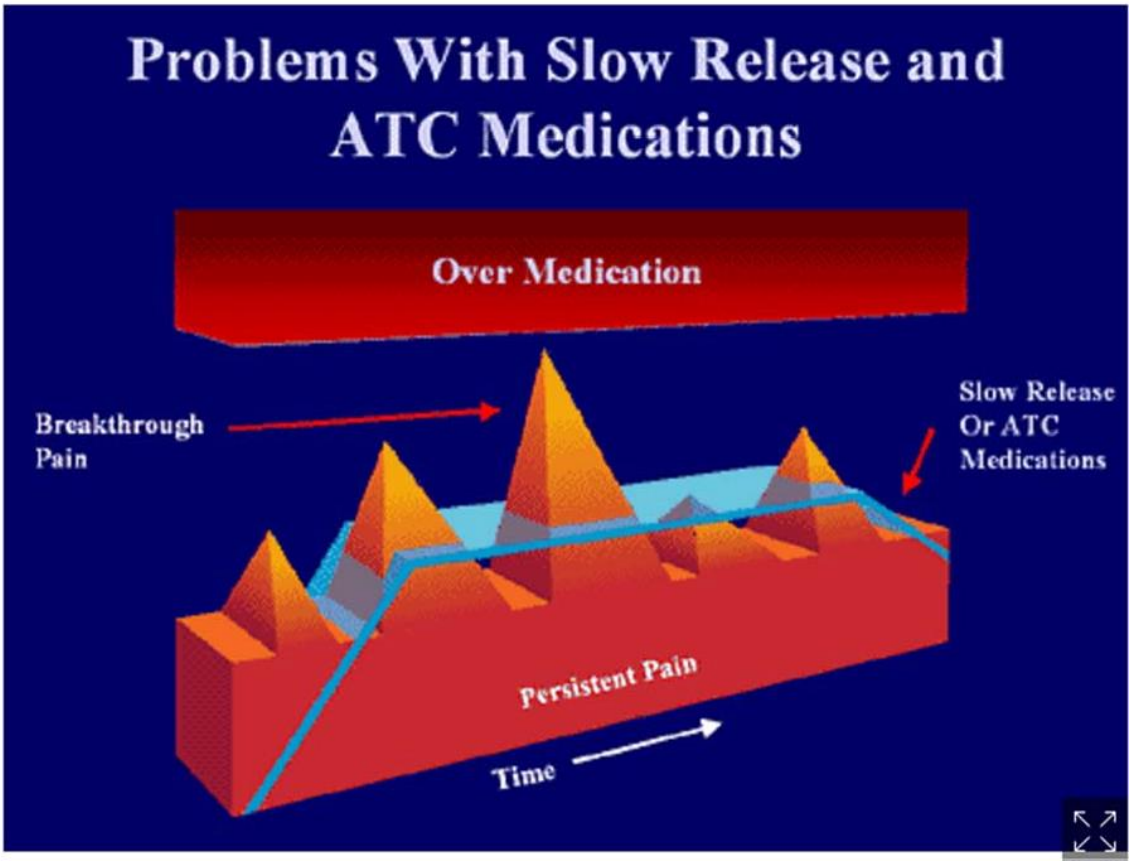
450. For example, a 2003 Cephalon-sponsored CME presentation titled, "Pharmacologic Management of Breakthrough or Incident Pain," posted on Medscape in February 2003, stated:

> [C]hronic pain is often undertreated, particularly in the noncancer patient population. . . . The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patient fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.[236]

451. Another Cephalon-sponsored CME presentation titled, "Breakthrough Pain: Treatment Rationale with Opioids" was available on Medscape starting September 16, 2003 and was given by a self-professed pain management doctor who "previously operated back, complex regional pain syndromes, the neuropathies, and interstitial cystitis." (One slide from that CME presentation is set forth below.) The presentation describes the pain process as a non-time-

[236] Michael J. Brennan et al., *Pharmacologic Management of Breakthrough or Incident Pain*, Medscape, https://www.medscape.org/viewarticle/449803 (last visited Sept. 18, 2019).

dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway."[237] The doctor lists fentanyl as one of the most effective opioids available for treating BTP, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned.



452. Dr. Stephen H. Landy ("Landy") authored a 2004 CME manuscript available on Medscape titled, "Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series." The manuscript preparation was supported by Cephalon. Landy describes the findings of a study of fentanyl citrate to treat migraine headache pain and

[237] Daniel S. Bennett, *Breakthrough Pain: Treatment Rationale With Opioids*, Medscape, https://www.medscape.org/viewarticle/461612 (last visited Sept. 26, 2019).

concluded that "OTFC rapidly and significantly relieved acute, refractory migraine pain in outpatients . . . and was associated with high patient satisfaction ratings."[238] Based on an analysis of publicly available data, Cephalon paid Landy approximately $190,000 in 2009-2010 alone, and in 2015-2016, Cephalon paid Landy another $75,000.

453. In 2006, Cephalon sponsored a review of scientific literature to create additional fentanyl-specific dosing guidelines titled, *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC®) Dosing Guidelines*.[239] The article purports to review the evidence for dosing and efficacy of oral transmucosal fentanyl citrate in the management of pain and produce dosing guidelines in both cancer and non-cancer patients. In pertinent part, it states:

> Oral transmucosal fentanyl citrate has a proven benefit in treating cancer associated breakthrough pain in opioid-tolerant patients with cancer, which is the Food and Drug Administration (FDA)-approved indication for Actiq. *Pain medicine physicians have also used OTFC successfully to provide rapid pain relief in moderate to severe noncancer pain in both opioid-tolerant and opioid-nontolerant patients*.[240]

454. Later in the article, the authors attempt to assuage doctors' concerns regarding possible overdose and respiratory distress in non-cancer patients by arguing "*[t]here is no evidence that opioid safety and efficacy differs in opioid-tolerant patients with chronic noncancer pain*." Regarding the use of fentanyl to treat non-opioid-tolerant patients, the article's authors stated:

> Alternatively, *OTFC might also be used cautiously and safely for* acute pain experienced by *patients who are not opioid tolerant*. *Parenteral opioids are routinely used for acute pain in patients who are not opioid tolerant*. Examples include episodic pain (*i.e.*, refractory migraine pain, recurrent renal calculi, etc.) and acute pain that follows surgery, trauma, or painful procedures (burn dressing

[238] Stephen H. Landy, *Oral Transmucosal Fentanyl Citrate for the Treatment of Migraine Headache Pain In Outpatients: A Case Series*, 44(8) Headache (2004), https://www.medscape.com/viewarticle/488337_2 (last visited Sept. 26, 2019).
[239] Gerald M. Aronoff et al., *Evidence-Based Oral Transmucosal Fentanyl Citrate (OTFC) Dosing Guidelines*, 6(4) Pain Med. 305-14 (Aug. 2005).
[240] *Id*.

> change, bone marrow aspiration, lumbar puncture). Assuming that clinical experience with IV morphine in patients who are not opioid tolerant can be extrapolated, OTFC should be safe and efficacious in such settings as well.[241]

455. Through its sponsorship of FSMB (*see supra* ¶ 167), Cephalon continued to encourage the prescribing of opioid medication to "reverse . . . and improve" patient function, attributing patients' displays of traditional drug-seeking behaviors as merely "pseudoaddiction."

456. Cephalon also disseminated its false messaging through speakers' bureaus and publications. For example, at an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Webster and others titled, "Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results." The presentation's agenda description states: "Most patients with chronic pain experience episodes of breakthrough pain (BTP), yet no currently available pharmacologic agent is ideal for its treatment." The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the "[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP."

457. Cephalon sponsored another CME presentation written by Webster and M. Beth Dove titled, "Optimizing Opioid Treatment for Breakthrough Pain" and offered on Medscape from September 28, 2007 through December 15, 2008. The presentation stated that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating BTP than pure opioid analgesics because of dose limitations on the non-opioid component.

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[241] *Id.*

458. Fine authored a Cephalon-sponsored CME presentation titled, "Opioid-Based Management of Persistent and Breakthrough Pain," with Drs. Christine A. Miaskowski and Michael J. Brennan. Cephalon paid to have this CME presentation published as a "Special Report" supplement of the journal *Pain Medicine News* in 2009.[242] The CME presentation targeted a wide variety of non-oncologist healthcare providers who treat patients with chronic pain with the objective of educating "health care professionals about a semi-structured approach to the opioid-based management of persistent and breakthrough pain," including the use of fentanyl. The CME presentation purported to analyze the "combination of evidence- and case-based discussions" and ultimately concluded:

> *All individuals with chronic, moderate to severe pain associated with functional impairment should be considered for a trial or opioid therapy, although not all of them will be selected.*[243]

459. Along with Purdue, Cephalon sponsored the APF's guide (*see supra* ¶ 187), which warned against the purported *under*-prescribing of opioids, taught that addiction is ***rare***, and suggested that opioids have "*no ceiling dose*" and are therefore the most appropriate treatment for severe pain. A summary of the February 12-16, 2008 AAPM annual meeting reinforced the message, promoted both by the AAPM and the APS, that "the undertreatment of pain is unjustified." It continued, *"Pain management is a fundamental human right* in all patients not only with acute postoperative pain but also *in patients suffering from chronic pain*.".[244]

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[242] Perry G. Fine et al., *Opioid-Based Management of Persistent and Breakthrough Pain*, Special Report (2009), https://www.yumpu.com/en/document/view/11409251/opioid-basedmanagement-of-persistent-and-breakthrough-pain/9.
[243] *Id.*
[244] Mohamed A. Elkersh & Zahid H. Bajwa, *Highlights From the American Academy of Pain Medicine 24th Annual Meeting*, 2(1) Advances in Pain Management 50-52 (2008).

460. Cephalon was one of several opioid manufacturers who collectively paid 14 of the 21 panel members who drafted the 2009 APS-AAPM opioid treatment guidelines.[245]

461. In the March 2007 article titled, "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate,"[246] published in the nationally circulated journal *Pain Medicine*, physicians paid by Cephalon (including Webster) described the results of a Cephalon-sponsored study seeking to expand the definition of BTP to the chronic, non-cancer setting. The authors stated that the "OTFC has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of the effect of BTP on the [quality of life] of noncancer pain patients."[247] The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cited Portenoy and recommended fentanyl for non-cancer BTP patients:

> In summary, BTP appears to be a clinically important condition in patients with *chronic noncancer pain* and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP *and the potential benefits of BTP-specific therapy* suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.[248]

462. Cephalon also sponsored, through an educational grant, the regularly published journal *Advances in Pain Management*. A single 2008 issue of the journal contained numerous articles from Portenoy, Dr. Steven Passik ("Passik"), Dr. Kenneth L. Kirsh ("Kirsh"), and Webster, all advancing the safety and efficacy of opioids. In an article titled, "Screening and

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[245] *See* Chou, *Clinical Guidelines*, *supra* n.87.
[246] Donald R. Taylor et al., *Impact of Breakthrough Pain on Quality of Life in Patients With Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment With Oral Transmucosal Fentanyl Citrate (OTFC, ACTIQ)*, 8(3) Pain Med. 281-88 (Mar. 2007).
[247] *Id*.
[248] *Id*.

Stratification Methods to Minimize Opioid Abuse in Cancer Patients," Webster expressed disdain for the prior 20 years of opioid phobia.

463. In another article from the same issue, "Appropriate Prescribing of Opioids and Associated Risk Minimization," Passik and Kirsh stated: "[c]hronic pain, currently experienced by approximately 75 million Americans, is becoming one of the biggest public health problems in the US." They assert that addiction is rare, that "[m]ost pain specialists have prescribed opioids for long periods of time with success demonstrated by an improvement in function" and that then-recent work had shown "that opioids do have efficacy for subsets of patients who can remain on them long term and have very little risk of addiction."[249]

464. In November 2010, Fine and others published an article presenting the results of another Cephalon-sponsored study titled, "Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study."[250] In that article, Fine explained that the 18-month "open-label" study "assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain." The article acknowledged that: (a) "[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades"; (b) the "widespread acceptance" had led to the publishing of practice guidelines "to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of

[249] Steven D. Passik & Kenneth L. Kirsh, *Appropriate Prescribing of Opioids and Associated Risk Minimization*, 2(1) Advances in Pain Management 9-16 (2008).
[250] Perry G. Fine et al., *Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study*, 40(5) J. Pain & Symptom Management 747-60 (Nov. 2010).

chronic pain"; and (c) those guidelines lacked "data assessing the long-term benefits and harms of opioid therapy for chronic pain."[251]

465. The article concluded: "[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable." That article concluded that the number of abuse-related events was "small."[252]

466. From 2000 forward, Cephalon has paid doctors nationwide millions of dollars for programs relating to its opioids, many of whom were not oncologists and did not treat cancer pain. These doctors included Portenoy, Webster, Fine, Passik, Kirsh, Landy, and others.

467. Cephalon's payments to doctors have resulted in studies that support its sales but are biased or irreparably flawed. For instance, and upon information and belief, the governmental whistleblower investigation into Actiq revealed that two studies touted by Cephalon had tested fewer than 28 patients and had no control group whatsoever.[253] A 2012 article evaluating the then-current status of transmucosal fentanyl tablet formulations for the treatment of BTP in cancer patients noted that clinical trials to date used varying criteria, that "the approaches taken . . . [did] not uniformly reflect clinical practice," and that "the studies ha[d] been sponsored by the manufacturer and so ha[d] potential for bias."[254]

468. Teva, which acquired Cephalon, repeatedly refused to produce information requested as part of a Senate investigation into opioid manufacturers and distributors. Senator McCaskill issued requests on July 26, 2017 and September 28, 2017. In a letter to Teva sent

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[251] *Id*.
[252] *Id*.
[253] Carreyrou, *Cephalon Used Improper Tactics*, *supra* n.231.
[254] Eric Prommer & Brandy Fleck, *Fentanyl transmucosal tablets: current status in the management of cancer-related breakthrough pain*, 2012(6) Patient Preference and Adherence 465-75 (June 25, 2012).

September 28, 2017, Senator McCaskill explained that "the company's decision to obstruct basic oversight on the opioid epidemic should deeply concern shareholders." On March 6, 2018, Senator McCaskill issued a press release castigating Teva for its continued refusal to comply with her requests: "Teva's refusal to cooperate with Congressional requests strongly suggests they have something to hide."[255] As of July 12, 2018, the date Senator McCaskill's third report titled, *Fueling an Epidemic: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, was published, Teva remained uncooperative.[256]

f) Cephalon Failed to Monitor and Report Suspicious Sales as Required.

469. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

470. Cephalon is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

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[255] Press Release, U.S. Senate Committee on Homeland Security & Governmental Affairs, McCaskill: Teva Is Stonewalling a Senate Investigation (Mar. 6, 2018), https://www.hsgac.senate.gov/media/minority-media/mccaskill-teva-is-stonewalling-a-senate-investigation.

[256] *Fueling an Epidemic, Report Three: A Flood of 1.6 Billion Doses of Opioids into Missouri and the Need for Stronger DEA Enforcement*, U.S. Senate Homeland Security & Governmental Affairs Committee, Ranking Member's Office at 1 (July 12, 2018), https://www.hsgac.senate.gov/ imo/media/doc/REPORT-Fueling%20an%20Epidemic-A%20Flood%20of%201.6%20Billion%20Doses%20of%20Opioids%20into%20Missouri%20and%20the%20Need%20for%20Stronger%20DEA%20Enforcement.pdf (hereinafter, "*July 2018 McCaskill Report*").

471. Cephalon failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Cephalon's failure to timely report these and other suspicious sales violated the CSA.

6. The Insys Co-Conspirators

472. Insys manufactures, markets, sells and distributes the following pharmaceutical drug nationwide:

Subsys (fentanyl)	Fentanyl sublingual spray; semi-synthetic opioid agonist, approved in 2012.	Schedule II

473. Subsys is indicated "for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy for their underlying persistent cancer pain."[257] The indication also specifies that "SUBSYS is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain." In addition, the indication provides that "[p]atients must remain on around-the-clock opioids when taking SUBSYS." Subsys is contraindicated for, among other ailments, the "[m]anagement of acute or postoperative pain including headache/migraine and dental pain." It is available in 100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg dosage strengths.

474. Insys' revenue is derived almost entirely from Subsys. According to its Form 10-K for 2015, Insys reported revenues of $331 million. Of that total, $329.5 million was derived from sales of Subsys. The majority of Insys' sales of Subsys are through wholesalers including

[257] The indication provides that "[p]atients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer."

AmerisourceBergen, McKesson, and Cardinal Health. In 2015, those wholesalers respectively comprised 20%, 17%, and 14% of Insys' total gross sales of Subsys, respectively.

475. According to Dr. Andrew Kolodny, executive director of Physicians for Responsible Opioid Prescribing and chief medical officer of the Phoenix House Foundation, fentanyl products are "'the most potent and dangerous opioids on the market.'"[258]

476. The dangers associated with Subsys are reflected by its extremely limited and specific indication, as it is approved solely for BTP in cancer patients already receiving opioids for persistent cancer-related pain.

477. Despite Subsys' limited indication and the potent danger associated with fentanyl, Insys falsely and misleadingly marketed Subsys to doctors as an effective treatment for back pain, neck pain, and other off-label pain conditions.[259] Moreover, as of June 2012, Insys defined BTP in cancer patients to include mild pain: a "flare of *mild-to*-severe pain in patients with otherwise stable persistent pain," based on a misleading citation to a paper written by Portenoy.[260] Insys trained and instructed its sales representatives to use the false definition of breakthrough pain and specifically to use a core visual aid, including the improper definition, whenever they detailed Subsys to a healthcare provider or provider's office.

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[258] Dina Gusovsky, *The pain killer: A drug company putting profits above patients*, CNBC (Nov. 5, 2015, 10:13 AM), http://www.cnbc.com/2015/11/04/the-deadly-drug-appeal-of-insyspharmaceuticals.html.

[259] *In the Matter of Insys Therapeutics, Inc.*, Notice of Unlawful Trade Practices and Proposed Resolution (July 10, 2015), https://www.documentcloud.org/documents/2195731-insysdoj.html.

[260] Portenoy's paper, "Breakthrough pain: definition, prevalence and characteristics," which was featured in the 1990 issue of *Pain*, actually defined breakthrough pain as "a transitory increase in pain to greater than moderate intensity (that is, to an intensity of 'severe' or 'excruciating'). . . on a baseline pain of moderate intensity or less." Russell K. Portenoy & Neil A. Hagen, *Breakthrough pain: Definition, prevalence and characteristics*, 40(3) Pain 273-81 (July 1990).

478. According to a 2014 article in *The New York Times*, only 1% of prescriptions for Subsys were written by oncologists. Approximately half the prescriptions were written by pain specialists, with others written by other specialists including dentists and podiatrists.[261]

a) Federal Investigation of Insys.

479. In 2018, the U.S. Department of Justice intervened in five lawsuits that were filed pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b), which alleged that Insys violated the Act due to its improper marketing practices of Subsys.[262]

480. In June 2019, Insys agreed to a settlement and deferred prosecution with the DOJ. It settled the civil cases for $195 million, and it agreed to pay a $2 million fine and $28 million in forfeitures, and plead guilty to five counts of mail fraud arising from kickbacks and bribes that were made as part of its illegal marketing practices.[263]

b) The Indictment of Insys Executives and the Arrest of Its Founder.

481. On December 8, 2016, several former Insys executives were arrested and indicted for conspiring to bribe practitioners in numerous states, many of whom operated pain clinics, in order to get them to prescribe Subsys. In exchange for bribes and kickbacks, the practitioners wrote large numbers of prescriptions for patients, most of whom were not diagnosed with cancer.[264]

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[261] Katie Thomas, *Doubts Raised About Off-Label Use of Subsys, a Strong Painkiller*, N.Y. Times (May 13, 2014), https://www.nytimes.com/2014/05/14/business/doubts-raised-about-off-label-use-of-subsys-a-strong-painkiller.html.

[262] Settlement Agreement, available at https://www.justice.gov/usao-ma/press-release/file/1170131/download.

[263] Press Release, Opioid Manufacturer Insys Therapeutics Agrees to Enter $225 Million Global Resolution of Criminal and Civil Investigations (June 5, 2019), https://www.justice.gov/opa/pr/opioid-manufacturer-insys-therapeutics-agrees-enter-225-million-global-resolution-criminal.

[264] Press Release, U.S. Attorney's Office for the District of Massachusetts, Pharmaceutical Executives Charged in Racketeering Scheme (Dec. 8, 2016), https://www.justice.gov/usao-

482. The indictment alleged that the former executives conspired to mislead and defraud health insurance providers, who were reluctant to approve payment for Subsys when it was prescribed for patients without cancer. In response, the former executives established a "reimbursement unit" at Insys, which was dedicated to assisting physicians by obtaining prior authorization for prescribing Subsys directly from insurers and PBMs. Insys' reimbursement unit employees were told to inform agents of insurers and PBMs that they were calling "from" or that they were "with" the doctor's office, or that they were calling "on behalf of" the doctor.

483. The executive defendants in the indictment include John Kapoor ("Kapoor"), Insys' former CEO and president, as well as the company's former vice president of sales, former national director of sales, former vice president of managed markets, and several former regional sales directors. On October 26, 2017, Kapoor—the billionaire founder, CEO, and chairman of Insys, who owns a 60% stake in the company—was also charged with fraud and racketeering and was accused of offering bribes to doctors to write large numbers of prescriptions for Subsys. Most of the patients who received the medication did not have cancer.[265]

484. The charges against all seven executives include alleged violations of the federal Anti- Kickback Law, the Racketeer Influenced and Corrupt Organizations ("RICO") statute, and conspiracy to commit wire and mail fraud, as well as allegations of bribery and defrauding insurers.

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ma/pr/pharmaceutical-executives-charged-racketeering-scheme (hereinafter, "Insys Indictment Press Release"); *United States v. Babich, et al.*, No. 1:16-cr-10343-ADB, ECF. No. 1 (D. Mass. Dec. 6, 2016), https://www.justice.gov/usao-ma/press-release/file/916681/download (hereinafter, "Insys Indictment").

[265] Michela Tindera, *Opioid Billionaire Arrested On Racketeering Charges*, Forbes (Oct. 26, 2017), https://www.forbes.com/sites/michelatindera/2017/10/26/opioid-billionaire-arrested-on-racketeering-charges/#14d33e606a00.

485. In May 2019, the defendants, including Kapoor and four top executives, were found guilty of conspiring to bribe doctors to prescribe Subsys.[266] They face possible sentences of up to 20 years for conspiracy to commit RICO and conspiracy to commit mail and wire fraud, as well as a fine of $250,000 or twice the amount of the pecuniary gain or loss. For the charge of conspiracy to violate the Anti-Kickback Law, the defendants face a sentence of up to five years in prison and a $25,000 fine.

486. The indictment details a coordinated, centralized scheme by Insys to illegally drive profits. The company defrauded insurers from a call center at corporate headquarters where Insys employees, acting at the direction of Insys' former CEO and vice president of managed markets, disguised their identity and the location of their employer and lied about patient diagnoses, the type of pain being treated, and the patient's course of treatment with other medication.

487. Harold H. Shaw ("Shaw"), special agent in charge of the FBI Boston field division, said in a statement, "[a]s alleged, these executives created a corporate culture at Insys that utilized deception and bribery as an acceptable business practice, deceiving patients, and conspiring with doctors and insurers."[267]

c) Insys Targeted Non-Cancer Treating Physicians and Funded False Publications and Presentations.

488. As set forth in the above-referenced indictment, Insys targeted and bribed practitioners in a number of ways. Insys bribed Subsys prescribers through strategic hires,

[266] Press Release, U.S. Attorney's Office for the District of Massachusetts, Founder and Four Executives of Insys Therapeutics Convicted of Racketeering Conspiracy, https://www.justice.gov/usao-ma/pr/founder-and-four-executives-insys-therapeutics-convicted-racketeering-conspiracy.

[267] Press Release, U.S. Department of Justice, Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering, https://www.justice.gov/opa/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

employing sales representatives and other employees at practitioners' behest and with the expectation that such hires would provide inroads with key practitioners. Further, the indictment alleges that Insys bribed practitioners through a sham speakers' bureau that was purportedly intended to increase brand awareness using peer-to-peer educational lunches and dinners.

489. Specifically, in June 2012, former executives began using in-person meetings, telephone calls, and texts to inform Insys sales representatives that the key to sales was using the speakers' bureau to pay practitioners to prescribe Subsys. As one of the company's vice presidents for sales texted one of his sales representatives about potential physicians for the speakers' bureau: "[t]hey do not need to be good speakers, they need to write a lot of [Subsys prescriptions]." The former Insys executives actively recruited physicians known to have questionable prescribing habits for these speakers' bureaus.[268]

490. Speakers' bureaus were often just social gatherings at high-priced restaurants involving neither education nor presentations. Frequently, they involved repeat attendees, including physicians not licensed to prescribe Subsys. Many of the speakers' bureaus had no attendees; sales representatives were instructed to falsely list names of attendees and their signatures on Insys' sign-in sheets.

491. Insys made thousands of payments to physicians nationwide for participating on these speakers' bureaus and for other services.

492. Moreover, Insys executives also charged practitioners who prescribed Subsys not only for cancer pain, but for all pain.

493. As set forth in the indictment, at one national speakers' bureau in or about 2014, Insys' then-vice president of sales stated:

[268] Insys Indictment, *supra* n.264, ¶ 38.

> These [doctors] will tell you all the time, well, I've only got like eight patients with cancer. Or, I only have, like, twelve patients that are on a rapid-onset opioids [sic]. Doc, I'm not talking about any of those patients. I don't want any of those patients. That's, that's small potatoes. That's nothing. That's not what I'm here doing. I'm here selling [unintelligible] for the breakthrough pain. If I can successfully sell you the [unintelligible] for the breakthrough pain, do you have a thousand people in your practice, a thousand patients, twelve of them are currently on a rapid-onset opioids [sic]. That leaves me with at least five hundred patients that can go on this drug.[269]

494. The indictment also alleges that, when agents of insurers or PBMs asked if a patient was being treated for BTP in cancer patients, Insys' reimbursement unit employees were instructed to answer using a written script, sometimes called "the spiel": "The physician is aware that the medication is intended for the management of breakthrough pain in cancer patients. The physician is treating the patient for their pain (or breakthrough pain, whichever is applicable)."[270]

495. Insys' former executives also tracked and internally circulated the number of planned and completed speakers' bureau events for each speaker, as well as the number of Subsys prescriptions each speaker wrote, the percentage of such prescriptions compared to those written for Subsys' competitor drugs, the total amount of honoraria paid to each speaker, and, for a period of time, an explicit calculation of the ratio of return on investment for each speaker. When a speaker did not write an appropriate number of Subsys prescriptions, as determined by Insys, the number of future events for which that speaker would be paid would be reduced unless and until he or she wrote more Subsys prescriptions.

496. In a press release issued when the indictment was announced, Shaw, the FBI Special Agent in charge of the Boston Field Division, linked the allegations to the national opioid epidemic:

> *As alleged, top executives of Insys Therapeutics, Inc. paid kickbacks and committed fraud to sell a highly potent and addictive opioid that can lead to*

[269] *Id.* ¶ 50.
[270] *Id.* ¶ 180.

> *abuse and life threatening respiratory depression . . . . In doing so, they contributed to the growing opioid epidemic and placed profit before patient safety. These indictments reflect the steadfast commitment of the FBI and our law enforcement partners to confront the opioid epidemic impacting our communities, while bringing to justice those who seek to profit from fraud or other criminal acts.*[271]

497. The Special Agent in Charge at the Defense Criminal Investigative Service in the Northeast Field Office, Craig Rupert, commented specifically on the effect the criminal activities had on members of the military: "Causing the unnecessary use of opioids by current and retired U.S. military service members shows disregard for their health and disrespect for their service to our country . . . ."[272]

498. On August 31, 2017, Arizona Attorney General Mark Brnovich filed a lawsuit alleging violations of the Arizona Consumer Fraud Act of 1967 ("ACFA") by Insys, two of its former employees, and three doctors. Attorney General Brnovich alleged that Insys and its two named employees – former Vice President of Sales Alec Burlakoff and former Manager of Reimbursement Services Elizabeth Gurrieri – engaged in numerous deceptive or unfair acts and practices, including those related to:

- using the Insys Reimbursement Center ("IRC"), which was designed to obtain prior authorization for Subsys from insurers and PBMs, misleading consumers about the prior authorization process and the IRC's practices;
- failing to warn consumers about IRC practices, even though Insys knew or had reason to know that healthcare professionals using the IRC would not be in a position to reduce foreseeable risks of harm due to the IRC's practices;
- providing healthcare professionals with false and misleading information, and concealing, suppressing or omitting material facts about the definition of "breakthrough cancer pain" and the FDA-approved uses of Subsys, in order to deceive healthcare professionals so that they would prescribe more Subsys;

[271] *Id.*
[272] *Id.*

- failing to warn consumers of the foreseeable risks of harm from Subsys and Insys' practices while knowing or having reason to know that healthcare professionals to whom Insys provided false and misleading information would not be in a position to reduce the foreseeable risks of harm; and

- providing sham "speaker fees" to healthcare practitioners to induce, and in exchange for, the healthcare practitioners writing Subsys prescriptions.

499. According to the complaint, between March 2012 and April 2017, the three defendant doctors wrote more than $33 million worth of Subsys prescriptions while being paid, on average, approximately $200,000 each in "speaker fees" by Insys.

500. According to the complaint, in order to be booked as speakers and receive speaker fees, doctors were required to have at least 20 patients on Subsys. Frequent prescribers of Subsys were "rewarded" by being paid in speakers fees, which served to "notice[]" "their support of Subsys" with "positive reinforcement."

501. On April 13, 2018, the DOJ, joined by the states of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Washington, Massachusetts, and Virginia, and the District of Columbia, filed a False Claims Act complaint against Insys, focusing on illegal kickbacks to doctors.

502. Similar to the claims in the ACFA litigation, the DOJ alleged: Since 2012, Insys has operated a "speaker program" through which it has paid Subsys prescribers to give speeches about Subsys to physicians and other healthcare professionals. Insys has pretended that these presentations were intended to provide potential Subsys prescribers with substantive medical information about the drug. In reality, many of these events have been mere pretexts for paying thousands of dollars in sham speaking fees to prescribers for the purpose of inducing them to prescribe Subsys. Many of these speeches have been attended only by the prescriber's own office

staff, by close friends who attended multiple presentations, or by people who were not medical professionals and had no legitimate reason for attending. Many of the "speeches" have not involved any actual substantive presentation by the purported "speaker." The events have often been held in expensive restaurants.[273]

d) Insys Failed to Monitor and Report Suspicious Sales as Required.

503. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

504. Insys is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

505. Insys failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Insys' failure to timely report these and other suspicious sales violated the CSA.

7. The Mallinckrodt Co-Conspirators

506. Mallinckrodt manufactures, markets, sells, and distributes pharmaceutical drugs nationwide. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

507. Among the drugs it distributes are the following:

[273] Complaint, *United States of America, et al. v. Insys Pharma., et al.*, No. 13-cv-05861 (C.D. Cal. Apr. 13, 2018) https://www.justice.gov/opa/press-release/file/1063051/download.

Exalgo (hydromorphone hydrochloride extended release)	Opioid agonist indicated for opioid-tolerant patients for management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options (*e.g.*, non-opioid analgesics) are inadequate. The FDA approved the 8, 12, and 16 mg tablets of Exalgo in March 2010 and 32 mg tablet in August 2012.	Schedule II
Roxicodone (oxycodone hydrochloride)	Brand-name instant-release form of oxycodone hydrochloride. Indicated for the management of pain severe enough to., require an opioid analgesic and for which alternative treatments are inadequate. Acquired from Xanodyne Pharmaceuticals in 2012. Strengths range up to 30 mg per pill. Nicknames include Roxies, blues, and stars.	Schedule II
Xartemis XR (oxycodone hydrochloride and acetaminophen)	The FDA approved Xartemis XR in March 2014 for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options are ineffective, not tolerated, or would otherwise be inadequate. It was the first extended-release oral combination of oxycodone and acetaminophen.	Schedule II
Methadose (methadone hydrochloride)	Branded generic product. Opioid agonist indicated for treatment of opioid addiction.	Schedule II
Morphine sulfate extended release	Generic product.	Schedule II
Fentanyl extended release	Generic product.	Schedule II
Fentanyl citrate	Generic product.	Schedule II
Oxycodone and acetaminophen	Generic product.	Schedule II
Hydrocodone bitartrate and acetaminophen	Generic product.	Schedule II
Hydromorphone hydrochloride	Generic product.	Schedule II
Hydromorphone hydrochloride extended release	Generic product.	Schedule II
Naltrexone hydrochloride	Generic product.	Schedule II
Oxymorphone hydrochloride	Generic product.	Schedule II
Methadone hydrochloride	Generic product.	Schedule II
Oxycodone hydrochloride	Generic product.	Schedule II

508. Mallinckrodt purchased Roxicodone from Xanodyne Pharmaceuticals in 2012.[274]

a) Mallinckrodt Funded False Publications and Presentations.

509. Like the Manufacturing Defendants and the Purdue co-conspirators, Mallinckrodt provided substantial funding to purportedly neutral organizations that disseminated false messaging about opioids.

510. For example, until at least February 2009, Mallinckrodt provided an educational grant to Pain-Topics.org, a now-defunct website that touted itself as "a noncommercial resource for healthcare professionals, providing open access to clinical news, information, research, and education for a better understanding of evidence-based pain-management practices."[275]

511. Among other content, the website included a handout titled, "Oxycodone Safety Handout for Patients," which advised practitioners that "[p]atients' fears of opioid addiction should be dispelled."[276] The handout included several false and misleading statements concerning the risk of addiction associated with prescription opioids:

> Will you become dependent on or addicted to oxycodone?
>
> - After a while, oxycodone causes physical dependence. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
>
> - This is not the same as addiction, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.[277]

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[274] *Mallinckrodt Announces Agreement with Xanodyne to Purchase Roxicodone*, Bus. Wire (Aug. 23, 2012), http://www.businesswire.com/news/home/20120823005209/en/Mallinckrodt-Announces-Agreement-Xanodyne-Purchase-Roxicodone%C2%AE.
[275] *Pain Treatment Topics*, Pain-Topics.org
[276] Lee A. Kral & Stewart B. Leavitt, *Oxycodone Safety Handout for Patients*, Pain-Topics.Org (June 2007), http://paincommunity.org/blog/wp-content/uploads/OxycodoneHandout.pdf.
[277] *Id*.

512. Additionally, the FAQ section of Pain-Topics.org contained the following false and misleading information downplaying the dangers of prescription opioid use:

> **Pseudoaddiction**—has been used to describe aberrant patient behaviors that may occur when pain is undertreated (AAPM 2001). Although this diagnosis is not supported by rigorous investigation, it has been widely observed that patients with unrelieved pain are very focused on obtaining opioid medications, and may be erroneously perceived as "drug seeking." Pseudo addiction can be distinguished from true addiction in that the behaviors resolve when the pain is effectively treated. Along with this, two related phenomena have been described in the literature (Alford et al. 2006):
>
> **Therapeutic dependence**—sometimes patients exhibit what is considered drug-seeking because they fear the reemergence of pain and/or withdrawal symptoms from lack of adequate medication; their ongoing quest for more analgesics is in the hopes of insuring a tolerable level of comfort.
>
> **Pseudo-opioid-resistance**—other patients, with adequate pain control, may continue to report pain or exaggerate its presence, as if their opioid analgesics are not working, to prevent reductions in their currently effective doses of medication.
>
> Patient anxieties about receiving inadequate pain control can be profound, resulting in demanding or aggressive behaviors that are misunderstood by healthcare practitioners and ultimately detract from the provision of adequate pain relief.[278]

513. In November 2016, Mallinckrodt paid Dr. Scott Gottlieb ("Gottlieb"), the new commissioner of the FDA, $22,500 for a speech in London, shortly after the U.S. presidential election.[279] Gottlieb has also received money from the Healthcare Distribution Alliance ("HDA"), an industry-funded organization that pushes the agenda of large pharmaceutical wholesalers, and he has often criticized efforts aimed at regulating the pharmaceutical opioid market.[280]

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[278] *FAQs*, Pain-Topics.org, https://web.archive.org/web/20080630030443/http://pain-topics.org/faqs/index1.php#tolerance (last visited Oct. 1, 2019).
[279] Lee Fang, *Donald Trump's Pick to Oversee Big Pharma Is Addicted to Opioid-Industry Cash*, The Intercept (Apr. 4, 2017, 2:15 PM), https://theintercept.com/2017/04/04/scott-gottlieb-opioid/.
[280] *Id*.

514. Mallinckrodt also made thousands of payments to physicians nationwide.

b) The DEA Investigates Suspicious Orders.

515. In 2008, the DEA and federal prosecutors launched an investigation into Mallinckrodt, charging that the company ignored red flags and supplied—and failed to report—suspicious orders for its generic oxycodone between 2008 and 2012.[281] The U.S. Attorney's office in Detroit handled the case. The investigation uncovered that from 2008 to 2012, Mallinckrodt sent, for example, 500 million tablets of oxycodone into a single state, Florida—"66 percent of all oxycodone sold in the state."[282] According to the internal government documents obtained by the *Washington Post*, Mallinckrodt's failure to report could have resulted in "nearly 44,000 federal violations and exposed it to $2.3 billion in fines."[283]

516. Despite learning from the DEA that generic opioids seized in a Tennessee drug operation were traceable to one of its Florida distributors, Sunrise Wholesale ("Sunrise") of Broward County, Mallinckrodt, in the following six weeks, sent 2.1 million tablets of oxycodone to Sunrise. In turn, Sunrise sent at least 92,400 oxycodone tablets to a single doctor over an 11-month period, who, in one day, prescribed 1,000 tablets to a single patient.[284]

517. Mallinckrodt's aggressive sales efforts continued unabated even as it was being investigated. In 2009, national account manager Victoria Borelli urged in an email to Steve Cochrane, vice president of sales for KeySource Medical, a distributor: "[i]f you are low, order more. If you are okay, order a little more, Capese?" She then joked, "destroy this email." In

[281] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, Wash. Post (Apr. 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?hpid=hp_hp-top-table-main_dea-645pm%3Ahomepage%2Fstory&utm_term=.c3c7673e35de.
[282] *Id.*
[283] *Id.*
[284] *Id.*

another email in January 2009, Borelli told Cochrane that 1,200 bottles of oxycodone 30 mg tablets had been shipped, to which Cochrane responded. "Keep 'em comin'!" "Flyin; out of there. It's like people are addicted to these things or something. Oh, wait, people are…" Borelli responded: "Just like Doritos keep eating. We'll make more."[285]

518. According to documents obtained by the *Washington Post*, investigators also found "scores of alleged violations" at Mallinckrodt's plant in Hobart, New York. Those violations included the failure to keep accurate records, to document transfers of drugs, and to secure narcotics.[286]

519. In May 2014, Mallinckrodt posted a video titled, "Red Flags: Pharmacists Anti-Abuse Video." The video is a thinly veiled attempt to divert responsibility for the opioid epidemic away from manufacturers and wholesalers, and toward individual pharmacists. The video was sponsored by the Anti-Diversion Industry Working Group, which is composed of Cardinal Health, Actavis, McKesson, Mallinckrodt, AmerisourceBergen, and Qualitest – all of whom are conveniently missing from the list of those responsible.[287]

520. In April 2017, Mallinckrodt reached an agreement with the DEA and the U.S. Attorneys for the Eastern District of Michigan and Northern District of New York to pay $35

[285] Scott Higham, Sari Horwitz, and Steven Rich, *Internal drug company emails show indifference to opioid epidemic*, Washington Post (July 19, 2019) (hereinafter "Internal drug company emails"), https://www.washingtonpost.com/investigations/internal-drug-company-emails-show-indifference-to-opioid-epidemic-ship-ship-ship/2019/07/19/003d58f6-a993-11e9-a3a6-ab670962db05_story.html?utm_term=.a3f264b7138e.
[286] *Id.*
[287] National Association of Boards of Pharmacy, *Red Flags*, YouTube (May 20, 2014), https://www.youtube.com/watch?v=WY9BDgcdxaM.

million to resolve a probe of its distribution of its opioid medications.[288] Mallinckrodt finalized the settlement on July 11, 2017, agreeing to pay $35 million while admitting no wrongdoing.[289]

c) Mallinckrodt Failed to Monitor and Report Suspicious Sales as Required.

521. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

522. Mallinckrodt is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

523. Mallinckrodt failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Mallinckrodt's failure to timely report these and other suspicious sales violated the CSA.

8. Actavis

524. Actavis manufactures, markets, sells, and distributes pharmaceutical drugs nationwide. Until it sold its portfolio of generic opioids to Teva, Actavis was among the largest U.S. suppliers of opioid pain medications.

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[288] Linda A. Johnson, *Mallinckrodt to Pay $35M in Deal to End Feds' Opioid Probe*, AP News (Apr. 3, 2017), https://www.apnews.com/28dbac05ce924d0a8b710b8ea55df5db.

[289] Press Release, U.S. Department of Justice, Mallinckrodt Agrees to Pay Record $35 Million Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders.

525. Among the drugs Actavis distributes or distributed during the times relevant to the allegations herein are the following:

Kadian (morphine sulfate, extended release)	Opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate. 20 mg, 50 mg, and 100 mg strengths approved by the FDA in 1996. 30 mg and 60 mg strengths approved by the FDA in 2001. 80 mg strength approved by the FDA in 2006. 10 mg and 200 mg strengths approved by the FDA in 2007. 40 mg, 70 mg, 130 mg, and 150 mg strengths approved by the FDA in 2012.	Schedule II
Norco (hydrocodone bitartate and Acetaminophen	Opioid agonist initially indicated for the relief of moderate to moderately severe pain. Later, indication amended to treat acute pain sever enough to require opioid analgesic and for which alternative treatments are inadequate. Norco was initially approved by the FDA in 1997.	Schedule III (1997-2014) Schedule II (2014-present)
Oxymorphone hydrochloride	Generic equivalent of Opana ER. Launched in 2013.	Schedule II
Morphine sulfate	Generic equivalent of Kadian. Launched in 2013.	Schedule II
Fentanyl citrate transdermal	Generic equivalent of Duragesic. Launched in 2007.	Schedule II

526. Actavis acquired Kadian from King Pharmaceuticals in 2008 for an amount up to $127.5 million, depending on quarterly sales-related milestones.

527. Actavis marketed and sold generic opioids until it sold its generic opioid portfolio for $40.5 billion to Teva in 2016.

a) The FDA Issued a Warning Letter to Actavis Concerning Extensive False and Misleading Claims in Kadian Marketing Materials.

528. On February 18, 2010, the FDA's Division of Drug Marketing, Advertising, and Communications issued a warning letter ("2010 Warning Letter") to Actavis concerning the marketing of Kadian. The letter warned that certain marketing materials for Kadian "are false or misleading because they omit and minimize the serious risks associated with the drug, broaden and fail to present the limitations to the approved indication of the drug, and present

unsubstantiated superiority and effectiveness claims" in violation of the FDCA and regulations promulgated thereunder. Specifically, the 2010 Warning Letter addressed two marketing materials: a Comparison Detailer and a Co-Pay Assistance Program brochure.

529. According to the 2010 Warning Letter, the marketing materials "present several effectiveness claims for Kadian but fail to present any contraindications, and also omit several warnings, precautions, drug interactions and adverse events" including by failing to include "warnings regarding potentially fatal abuse of opioids [and] use by individuals other than the patient for whom the drug was prescribed."

530. The 2010 Warning Letter also states that the Comparison Detailer "fails to present risk information with a prominence and readability that is reasonably comparable to the presentation of benefit information." Whereas "the first five of the six pages of the Comparison Detailer prominently present efficacy claims about Kadian using large, bolded headers and claims surrounded by a significant amount of white space . . . using colorful charts and graphs," "the only specific risk information presented is relegated to the back cover . . . in a small font . . . beneath a large, bolded headline claim that presents a benefit claim."

531. The 2010 Warning Letter provides that the effect of these presentations "minimizes the risks associated with Kadian and misleadingly suggests that Kadian is safer than has been demonstrated."

532. Further, the 2010 Warning Letter states that Kadian promotional materials were misleading because they "present broad claims about the drug's use in treating pain, therefore implying that Kadian is appropriate for use in a broader range than it is approved to treat." The 2010 Warning Letter cites the following examples from the Comparison Detailer:

- "Allow for less breakthrough pain and more consistent pain relief for patients."

- "Better pain control . . . ."
- "Improved pain control . . . ."
- "Allow patients to live with less pain . . . ."
- "Less Pain. More options."

533. According to the 2010 Warning Letter, "[t]hese presentations in the Comparison Detailer suggest that Kadian is appropriate for patients with broader types of pain than the drug is indicated for."

534. The 2010 Warning Letter found similar problems in the Co-Pay Assistance Program brochure, which included the following statements (emphases in original):

- "**Why is pain management important?** Pain management is a large part of your overall health care plan. Many Americans suffer from chronic or ongoing pain . . . Managing your pain the right way begins by talking to your healthcare provider. Discover the cause of your pain by taking note of what makes your pain start and what makes it worse."
- "**What is chronic pain?** Chronic pain is ongoing and can last longer than 6 months. Chronic pain can be mild or severe. . . ."
- "**How can I treat my chronic pain?** To help manage your pain, your healthcare provider will determine what level of pain control you need. Depending on what kind of pain you have and how it affects your life, your healthcare provider will choose a drug that works just for you."

535. The 2010 Warning Letter states that these statements "suggest[] that patients with broader types of chronic pain than the drug is indicated for are appropriate candidates for Kadian therapy, when this is not the case. . . . Kadian is *only* appropriate for a very limited patient population who experience pain." (Emphasis in original.) It continues, "[i]n addition, the partial indication included on the back cover of the Co-Pay Assistance Program brochure, unlike the chronic pain information, is written in technical medical language that is not likely to be easily understood by consumers."

536. Next, the 2010 Warning Letter identifies unsubstantiated superiority claims, including that Kadian "[a]llow[s] for less breakthrough pain and more consistent pain relief for patients" and asks, "Why settle for generic MS Contin tablets . . . When you can prescribe the benefits of KADIAN capsules?" According to the Letter, these "claims and presentations misleadingly imply that Kadian has been shown to be superior to MS Contin or generic controlled-release morphine" but the "FDA is not aware of ***any*** substantial evidence or substantial clinical expertise that supports these claims and presentations." (Emphasis in original.)

537. The 2010 Warning Letter also identifies the following claims "supported by a historically controlled study of inadequate design, completely lacking any concurrent control"; "[b]etter pain control and improved sleep scores"; "[i]mproved pain control and sleep scores in patients treated with KADIAN who were previously on CR morphine tablets"; and "[a]llow patients to live with less pain and get adequate rest with less medication." The 2010 Warning Letter states that the trial identified in support of these claims "clearly do[es] not support any conclusion that Kadian is superior to alternative treatments in pain or sleep measures."

538. Further, the 2010 Warning Letter focuses on the Comparison Detailer's inclusion of dosing claims comparing Kadian with MS Contin and Avinza. The Detailer claims that Kadian presents "[f]ewer barriers to prescribing" because "[t]he unique dosing flexibility of KADIAN gives you more options with morphine" than does MS Contin or Avinza. However, "the FDA is unaware of any substantial evidence or substantial clinical experience to support the claim that the above dosing characteristics allow Kadian to have 'fewer barriers to prescribing' (the meaning of which is not clear) as compared to other extended-release morphine products."

539. In conclusion, the 2010 Warning Letter found that the Comparison Detailer and Co-Pay Assistance Program brochure "misbrand Kadian in violation of the [FDCA]."

b) Actavis Failed to Monitor and Report Suspicious Sales as Required.

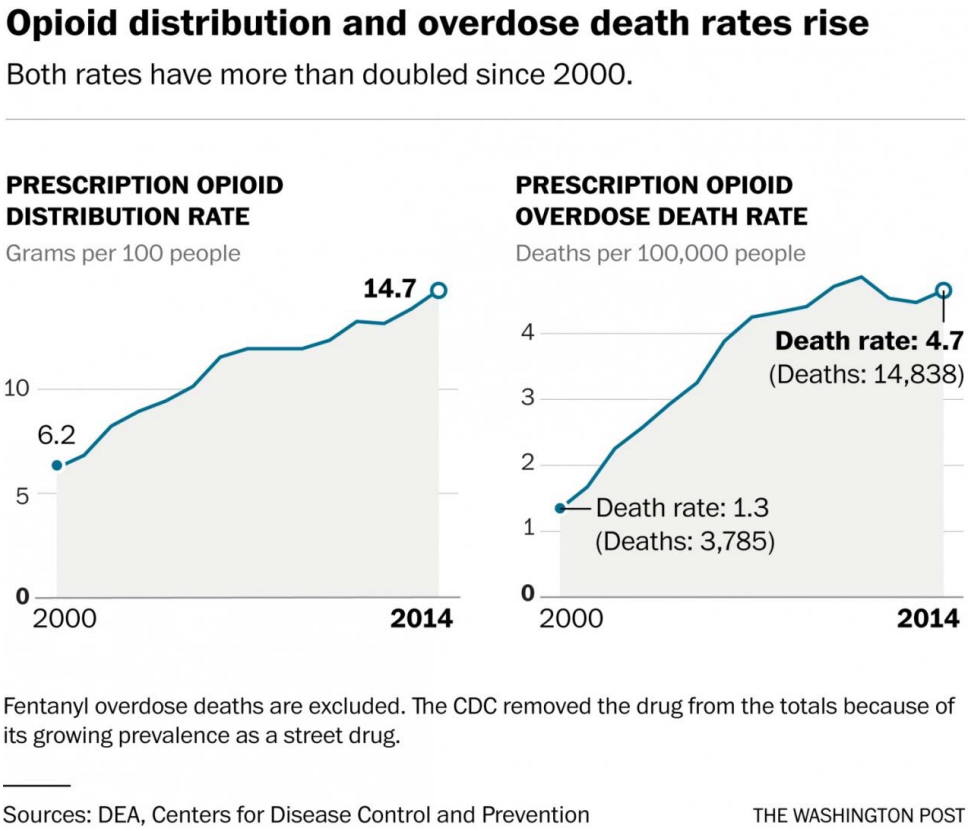
540. The federal CSA imposes on all "registrants" the obligation to design and operate a system to monitor suspicious orders of controlled substances and requires the registrant to notify the DEA field division office in its area of any suspicious orders. "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

541. Actavis is a "registrant" under the federal CSA. 21 C.F.R. §1300.02(b) defines a registrant as any person who is registered with the DEA under 21 U.S.C. §823. Section 823, in turn, requires manufacturers of Schedule II controlled substances to register with the DEA.

542. Actavis failed to design and operate a system to monitor suspicious orders of controlled substances and/or failed to notify the appropriate DEA field division of suspicious orders. Actavis's failure to timely report these and other suspicious sales violated the CSA.

D. The Distributor Defendants Failed to Track and Report Suspicious Sales as Required by Federal Law.

543. Manufacturers rely upon wholesale distributors to distribute their drugs. The distributors serve as middlemen, sending billions of doses of opioid pain pills to pharmacists, hospitals, nursing homes and pain clinics. According to the CDC, the increased distribution of opioids directly correlates to increased overdose death rates:



544. On October 23, 2017, CBS aired an episode of *60 Minutes* featuring former DEA agent Joe Rannazzisi ("Rannazzisi"), who blamed the Distributor Defendants for killing people by violating the CSA requirement to report suspicious orders:

> **RANNAZZISI**: This is an industry that's out of control. What they wanna do, is do what they wanna do, and not worry about what the law is. And if they don't follow the law in drug supply, people die. That's just it. People die.
>
> * * *
>
> This is an industry that allowed millions and millions of drugs to go into bad pharmacies and doctors' offices, that distributed them out to people who had no legitimate need for those drugs.
>
> **[INTERVIEWER]**: Who are these distributors?
>
> **RANNAZZISI**: The three largest distributors are Cardinal Health, McKesson, and AmerisourceBergen. They control probably 85 or 90 percent of the drugs going downstream.

> **[INTERVIEWER]**: You know the implication of what you're saying, that these big companies knew that they were pumping drugs into American communities that were killing people.
>
> **RANNAZZISI**: That's not an implication, that's a fact. That's exactly what they did.[290]

545. Jim Geldhof ("Geldhof"), a 40-year veteran of the DEA who ran investigations in the Detroit field office, corroborated Rannazzisi's account, saying that the wholesalers are "absolutely" responsible for the opioid epidemic:

> **[INTERVIEWER]**: These companies are a big reason for this epidemic?
>
> **GELDHOF**: Yeah, absolutely they are. And I can tell you with 100 percent accuracy that we were in there on multiple occasions trying to get them to change their behavior. And they just flat out ignored us.[291]

1. McKesson.

546. McKesson, headquartered in San Francisco, is a wholesale pharmaceutical distributor of controlled and uncontrolled prescription medications, including opioids. It is the largest pharmaceutical drug distributor in the United States. It distributes pharmaceuticals through a network of distribution centers across the country. McKesson ranked fifth on the 2017 Fortune 500 list, with over $192 billion in revenues.

547. McKesson supplies various United States pharmacies an increasing amount of prescription opioids, products frequently misused that are at the heart of the current opioid epidemic.

548. McKesson distribution centers are required to operate in accordance with the statutory provisions of the CSA. The regulations promulgated under the CSA include a

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[290] Bill Whitaker, *Ex-DEA Agent: Opioid Crisis Fueled by Drug Industry and Congress*, CBS News (Jun. 17, 2018), https://www.cbsnews.com/news/60-minutes-ex-dea-agent-opioid-crisis-fueled-by-drug-industry-and-congress/.
[291] *Id*.

requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

549. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

550. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but nevertheless failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers—*i.e.*, orders that are unusual in their frequency, size, or in some other way. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence of its new or existing customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the CSMP.

551. In 2011, McKesson's then-director of regulatory affairs, David B. Gustin, told his colleagues that he was concerned about the "number of accounts we have that have large gaps between the amount of Oxy or Hydro they are allowed to buy … and the amount they really need … This increases the 'opportunity' for diversion by exposing more product for introduction into the pipeline than may be used for legitimate purposes."[292]

[292] Internal drug company emails, *supra* n.285.

552. In 2013, the DEA again began investigating reports that McKesson was failing to maintain proper controls to prevent the diversion of opioids and accused McKesson of failing to design and use an effective system to detect "suspicious orders" from pharmacies for powerful painkillers such as oxycodone, as required by the CSA. Nine DEA field divisions and 12 U.S. Attorneys General built a case against McKesson for the company's role in the opioid crisis, which David Schiller ("Schiller"), then Assistant Special Agent in Charge for the Denver Field Division and leader of the DEA team investigating McKesson, called "the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration."[293]

553. On December 17, 2017, CBS aired an episode of *60 Minutes* featuring Assistant Special Agent Schiller, who described McKesson as a company that killed people for its own financial gain and blatantly ignored the CSA requirement to report suspicious orders:

> **SCHILLER**: If they woulda stayed in compliance with their authority and held those that they're supplying the pills to, the epidemic would be nowhere near where it is right now. Nowhere near.
>
> * * *
>
> They had hundreds of thousands of suspicious orders they should have reported, and they didn't report any. There's not a day that goes by in the pharmaceutical world, in the McKesson world, in the distribution world, where there's not something suspicious. It happens every day.
>
> **[INTERVIEWER]**: And they had none.
>
> **SCHILLER**: They weren't reporting any. I mean, you have to understand that, nothing was suspicious?[294]

[293] Bill Whitaker, *Whistleblowers: DEA Attorneys Went Easy on McKesson, the Country's Largest Drug Distributor*, CBS News (Dec. 17, 2017), https://www.cbsnews.com/news/whistleblowers-dea-attorneys-went-easy-on-mckesson-the-countrys-largest-drug-distributor/.
[294] *Id*.

554. Indeed, according to the DOJ, McKesson continued to fail to report suspicious orders between 2008 and 2012, in violation of the company's settlement with the DOJ, and never fully implemented or followed the monitoring program required under the terms of the settlement to which it agreed.

555. On January 17, 2017, in one of the most severe sanctions ever agreed to by a distributor, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan, and Florida) to settle allegations that the company violated federal law. As part of the 2017 agreement, McKesson acknowledged:

> at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA.[295]

2. Cardinal Health.

556. Cardinal Health describes itself as a global integrated healthcare services and products company. It generated $121.5 billion in total revenue during fiscal year 2016 (ended June 30, 2016). It is ranked 15th on the 2017 Fortune 500 list of top United States companies with revenues of over $121 billion.

557. Cardinal Health has two operating segments: pharmaceutical and medical. Its pharmaceutical segment, at issue in this action, distributes branded and generic pharmaceutical, special pharmaceutical, over-the-counter, and consumer products in the United States. Of Cardinal Health's $121.5 billion in revenue during fiscal year 2016, $109.1 billion was derived from the pharmaceutical operating segment.

[295] McKesson Settlement Agreement and Release, 5 (Jan. 5, 2017), available at https://www.justice.gov/opa/press-release/file/928471/download.

558. Cardinal Health distributes pharmaceuticals through a network of distribution centers across the country. Cardinal Health's largest customer is CVS Health ("CVS"), which accounted for 25% of Cardinal Health's fiscal year 2016 revenue.

559. Cardinal Health distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

560. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the CSA in Maryland, Florida, and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.[296]

561. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

- "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";
- "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required

[296] Earlier in 2016, CVS also agreed to pay the United States $8 million to resolve violations of the CSA by its Maryland pharmacies. According to the settlement agreement, CVS admitted that between 2008 and 2012, certain of its Maryland pharmacies dispensed oxycodone, fentanyl, hydrocodone and other pharmaceuticals in violation of the CSA because the drugs were dispensed without ensuring that the prescriptions were issued for legitimate medical purposes. Press Release, Cardinal Health Agrees to $44 Million Settlement for Alleged Violations of Controlled Substances Act, https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act.

by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

- "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305."

562. The settlement agreement was announced by the U.S. Attorney for the District of Maryland, Rod J. Rosenstein ("Rosenstein"), and the DEA Special Agent in Charge – Washington Field Division, Karl C. Colder ("Colder"). In the press release, Colder confirmed that the settlement primarily concerned the opioid oxycodone:

> DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy . . . . Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety . . .[297]

3. AmerisourceBergen.

563. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of approximately 20% of all pharmaceuticals sold and distributed in the United States through a network of 26 pharmaceutical distribution centers. It ranked 11th on the Fortune 500 list in 2017, with over $146 billion in annual revenue.

564. AmerisourceBergen distribution centers are required to operate in accordance with the statutory provisions of the CSA and the regulations promulgated thereunder, 21 C.F.R. §1300, *et seq.* The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances as that term is

[297] *Id.*

defined in the regulation. *See* 21 C.F.R. §1301.74(b). The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. §1301.74(b). *See* 21 U.S.C. §842(a)(5) & (c)(1)(B).

565. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws, as well as the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012.[298] AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period. Moreover, public documents also demonstrate that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants, including AmerisourceBergen, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis.

E. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids

566. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into

[298] Eric Eyre, *Drug firms poured 780M painkillers into WV amid rise of overdoses*, Charleston Gazette-Mail (Dec. 17, 2016), https://www.wvgazettemail.com/news/legal_affairs/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_99026dad-8ed5-5075-90fa-adb906a36214.html.

communities, they continued to participate in the oversupply and profit from it.

567. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it and contributed substantially to the diversion problem.

568. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, the National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided other Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have used to help stop diversion but failed to do so. In 2010, for example, Walgreen's fiscal year 2010 SEC Form 10-K disclosed that it recognizes "purchased prescription files" as "intangible assets" valued at $749,000,000.[299] In addition, Walgreens's own advertising has acknowledged that Walgreens has centralized data such that customers' "complete prescription records" from Walgreens's "thousands of locations nationwide" are "*instantly available*."

569. Similarly, CVS's Director of Managed Care Operations, Scott Tierney, testified that CVS's data vendors included IMS Health, Verispan, and Walters Kluwers and that CVS

[299] Walgreen Co. and Subsidiaries Annual Report for the Year Ended August, 31, 2010, SEC.gov, available at https://www.sec.gov/Archives/edgar/data/104207/000010420710000098/exhibit_13.htm (last visited Oct. 22, 2020).

used the vendors for "analysis and aggregation of data" and "some consulting services." He also testified that CVS would provide the vendors with "prescriber level data, drug level data, plan level data, [and] de-identified patient data."[300]

570. Each of the National Retail Pharmacies had complete access to all prescription opioid dispensing data related to its pharmacies across the United States, complete access to information revealing the doctors who prescribed the opioids dispensed in its pharmacies and the size and frequency of their prescriptions, and complete access to information revealing the customers who filled or sought to fill prescriptions for opioids in its pharmacies. Each of the National Retail Pharmacies likewise had complete access to information revealing the geographic location of out-of-state doctors whose prescriptions for opioids were being filled by its pharmacies.

1. The National Retail Pharmacies Have a Duty to Prevent Diversion

571. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring, and reporting suspicious activity.

572. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who

[300] Joint Appendix in *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 687134 (U.S.) *245-46 (Feb. 22, 2011).

fills the prescription." Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

573. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies how to identify suspicious orders and other evidence of diversion.

574. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

575. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use, but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look "too good" or where the prescriber's handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

576. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

577. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular

stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

578. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

579. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly.

580. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

581. Upon information and belief, this problem was compounded by the Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

582. Upon information and belief, the National Retail Pharmacies also failed to

adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids, or to adequately use data available to them to do statistical analyses to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

583. Upon information and belief, the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs; and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

584. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

585. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

586. The National Retail Pharmacies were, or should have been, fully aware that the quantity of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. Defendants Failed to Maintain Effective Controls Against Diversion

587. As described further below, the National Retail Pharmacies failed to fulfill their

legal duties and instead, routinely distributed and/or dispensed controlled substances while ignoring red flags of diversion and abuse.

a) CVS

588. CVS is one of the largest companies in the world, with annual revenue of more than $150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

(1) CVS lacked a genuine Suspicious Order Monitoring system for much of the relevant time.

589. CVS distribution centers, in tandem with outside wholesalers, such as Cardinal, supplied opioids to CVS pharmacy stores until October 2014. CVS self-distributed hydrocodone and hydrocodone combination products to its own stores, of which CVS had approximately 6,000 by 2006 and 9,700 by 2014. Hydrocodone (HCP) was rescheduled to FDA Schedule 2 status on October 6, 2014, and CVS ceased self-distributing hydrocodone the same day.

590. CVS pharmacies nationwide placed orders with CVS distribution centers through CVS's central mainframe computer ordering system.

591. Before 2009, CVS lacked any meaningful suspicious order monitoring ("SOM") system. Instead CVS relied on the gut instincts of the pickers and packers of the drugs in the distribution center – workers responsible for pulling items off distribution shelves for delivery to pharmacy stores – to identify "really big" orders that they believed were to large to be legitimate.

592. Moreover, CVS lacked a training program to train its pickers and packers on how to identify orders which were unusual in size, frequency, or pattern. CVS also lacked any

written policies, procedures, or protocols with respect to the pickers' and packers' obligations until August 2013. And there were no formal job requirements to be employed as a picker and packer.

593. In 2007, with the help of an outside consultant, CVS began work on a Standard Operating Procedure ("SOP") Manual that was intended to cover all facets of DEA controlled substances compliance, including suspicious order monitoring. However, as of the summer of 2010, neither the final manual nor the SOM section was complete. Internal documents from that time acknowledge that CVS was "still in the process of writing the suspicious order monitoring section of this standard operating procedure." In fact, the section of the Standard Operating Procedures for SOM states "BEING DEVELOPED AND WRITTEN."

594. Drafts of the SOP Manual, meanwhile, show CVS understood, or should have understood, that the status quo was unacceptable. The draft manual provides that: "CVS is responsible for ensuring compliance with DEA regulatory requirements, and that responsibility cannot be abdicated or transferred to anyone else." Despite this acknowledgement, when the first version of the SOP Manual was issued in December 2007 and for multiple revisions thereafter, the SOM section remained incomplete. As John Mortelliti, CVS's Director of Loss Prevention, wrote in November 2009, this had become "a big issue with CVS and the DEA," and he was "trying to get a rough draft SOM SOP" before a DEA meeting.

595. On August 24, 2010, the DEA initiated an audit and investigation of CVS Indiana for its distribution practices. The next day, CVS Pharmacy, Inc. sent a new SOP, which included for the very first time, a policy on SOM.

596. It was only in 2009 that CVS began using a computer algorithm that flagged potentially suspicious orders needing additional investigation. CVS called the output of the

flagged orders an Item Review Report ("IRR"). An outside vendor developed the program for CVS.

597. Originally, the vendor designed the algorithm to identify orders with a score of 0.15 or higher as potentially suspicious. (The higher the score, the more suspicious the order.) Between in the summer of 2010, Mortelliti adjusted the score threshold from 0.15 to 0.65, which caused fewer suspicious orders to be flagged for investigation. On February 8, 2011, the algorithm designer delivered to CVS a completely retuned SOM algorithm, which reverted the score threshold to 0.15. Afterward, CVS again raised the score to 0.65.

598. The IRRs were CVS's primary SOM process. As a CVS corporate representative explained on behalf of the company, for the most part, if an order was not flagged as suspicious under the IRR system, there would be no due diligence of that order.

599. CVS's SOM algorithm failed to factor in outside vendor orders. In other words, CVS's SOM system would not track how many opioids CVS was ordering from third party distributors such as Cardinal when evaluating whether to distribute opioids to one of its pharmacies. CVS knew this was a problem, as a "[s]tore may order a little from both the OV [outside vendor] and DC [CVS distribution center] to stay under the radar." It also knew that excluding outside vendor data meant CVS "may ship a potentially reportable suspicious order from [its] DC." Stores, including one that had a "68,000 hydrocodone pill loss," could also place telephone orders to outside vendors, into which there was "no visibility . . . until a later time." This deficiency is particularly glaring because, at a corporate level, CVS had full access to the orders its pharmacies placed to outside vendors.

600. Acknowledging the ineffectiveness and deficiencies within its SOM system, CVS hired new consultants in 2012 to troubleshoot its existing SOM systems for the purpose of

either fixing the deficient system or developing a new SOM system to attempt to become compliant with the law.

601. Still, as late as July 2013, internal e-mail reflects that CVS's primary tool for investigating suspicious orders relied on data that was months or even years old, making any analysis "for the most part, irrelevant and pointless."

602. Not until mid to late 2014 did CVS fully implement a new SOM system, but even then, CVS encountered problems in evaluating suspicious orders for opioids. CVS implemented a new SOM system in the Indianapolis distribution system in March of 2014. The deployment was delayed due to system data feed issues that created inaccuracies in the SOM historical data. A risk analysis of the new system was conducted in June 2014, and the SOM system's risk level was determined to be high in the following categories: (1) inconsistent due diligence in SOM analysts reaching out to stores to investigate suspicious orders; (2) inconsistency in documenting due diligence investigations of suspicious orders; (3) lack of engagement by the Management Team; (4) lack of communication between the SOM Management Team and SOM analysts; (5) lack of resources to handle the rollout of the new SOM system to all distribution centers; and (6) lack of clarity in how the new SOM system is identifying suspicious orders. That year, CVS stopped distributing opioids at the wholesale level.

603. Meanwhile, on August 5, 2013, the DEA had begun an audit and investigation of the CVS distribution center in Indiana, focused on CVS's failure to maintain a SOM program for controlled substances. In response to queries from the DEA, CVS wrote a letter to the DEA revealing it had only stopped seven suspicious orders across the entire country as of November 21, 2013. Right before sending the letter, its author, Mark Nicastro, head of the CVS

distribution center in Indiana, conceded internally that "I wish I had more stopped orders that went back further." While Mr. Nicastro was drafting the letter, he could not locate the SOP for SOM, writing to his colleague, Pam Hinkle, Senior Manager for Logistics, Quality, and Compliance for CVS, "For the life of me I can't find the SOP for SOM. Can you send me an electronic copy please? I have been on the logistics website, looked through hundreds of e-mails, nothing. I'm surprised it is not on the website." Mr. Hinkle responded that she too was unsure of the final version of the SOP SOM. CVS ultimately sent the wrong version of the SOP SOM to the DEA.

604. In May 2014, CVS had a closing meeting with the DEA related to the distribution center audit. According to handwritten notes from a CVS employee who attended the meeting, the "most serious" violation is "failure to design" a SOM system. An internal CVS e-mail summarizing the meeting made a similar statement: DEA determined that CVS "faile[d] to maintain an SOM program."

605. The DEA issued its closing letter concluding that CVS failed to design and maintain a system to detect and report suspicious orders for Schedule III-V Controlled Substances as required by 21 U.S.C. §§ 821, 823(e)(1), and 21 C.F.R. § 1301.73(b), in violation of 2 U.S.C. § 842(a)(5).

(2) CVS failed to perform due diligence.

606. All orders that appeared on the IRR required a thorough due diligence investigation, but CVS only performed appropriate due diligence on a very small percentage of them. From early/mid-2009 through early 2011, one employee, Mortelliti, "was taking the first pass through the IRR himself." According to CVS's corporate witness, "Mr. Mortelliti's practice would have been to review the report on a daily basis and determine whether items on

the report warranted further review and due diligence and conduct review and due diligence as he deemed appropriate." At certain times in 2013, CVS had only one full-time employee in the position of "SOM analyst" reviewing all potentially suspicious orders for every pharmacy in the country. The SOM system would identify orders as potentially suspicious based on a number of factors, but the CVS SOM analyst would conduct an "in depth" dive on only a small subset of those orders. In fact, the SOM program could identify as many as 1,000 suspicious orders a day, and the CVS employee would do a "deep dive" on only one to six orders per day.

607. CVS's SOM policy specified that if multiple orders for the same store are flagged during the same month, all orders after the first order will not be investigated and will be automatically released based on the release of the first order.

(3) CVS failed to implement effective policies and procedures to guard against diversion from its retail stores.

608. By 2009, CVS Pharmacy, Inc. owned and/or operated more than 9,000 pharmacies in the United States. According to its website, CVS now has more than 9,900 retail locations. At all relevant times, CVS pharmacies sold controlled substances, including FDA Schedule II and FDA Schedule III controlled substances, i.e., opiate narcotics or opioids.

609. "CVS Corporation," not any individual CVS store, is the DEA registrant for each of CVS's pharmacies across the country. CVS renews the DEA licenses for its pharmacies through a "Registration Chain Renewal." From October 2013 through December 2016, CVS headquarters paid more than $5 million to renew the licenses for 7,597 CVS locations.

610. As described above, until October 6, 2014, CVS pharmacies ordered and were supplied FDA Schedule III hydrocodone combination products (HCPs) from a combination of outside vendors and CVS distribution centers. CVS pharmacies also received Schedule II

opioids from outside vendors, with Cardinal acting as its exclusive outside supplier for the entire period for which data is available. Upon information and belief, McKesson also acts or has acted as an outside vendor for CVS.

611. CVS Pharmacy, Inc. instituted, ran, directed and staffed with its own employees the majority of the SOM functions for its pharmacy stores.

612. CVS lacked meaningful policies and procedures to guide its pharmacy staff in maintaining effective controls against diversion, even as they evolved over time. It was not until 2012 that CVS created guidelines explaining in more detail the "red flags" or cautionary signals that CVS pharmacists should be aware of to prevent diversion and to uphold their corresponding responsibilities to ensure that all dispensed controlled substances are issued for a legitimate medical purpose.

613. CVS failed to use data held at the corporate level to assist pharmacists in evaluating red flags of diversion. CVS's later dispensing policies and procedures make clear that for the majority of the time CVS has been engaged in the sale and dispensing of opioids, there was no meaningful integration of data and information that was within the possession and control of CVS corporate personnel.

614. Notably, with respect to CVS's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Opinion and Order [Denying CVS's Motion for Summary Judgment], MDL No. 2804, Doc. 3099 (N.D. Ohio Jan. 27, 2020).

b) Walgreens

615. Walgreens is the second-largest pharmacy store chain in the United States behind CVS, with annual revenue of more than $118 billion. According to its website, Walgreens operates more than 8,100 retail locations and filled 990 million prescriptions on a 30-day adjusted basis in fiscal 2017.

616. Acting as both a distributor and a retail pharmacy chain, Walgreens also self-distributed opioids to its own individual Walgreens pharmacies. Although Walgreens had visibility into red flags of diversion due to its vertically integrated distribution and dispensing practices, it failed to take these factors into account in its SOM program during the vast majority of the time it was distributing prescription opioids. Moreover, its program was wholly inadequate and did not fulfill its duties to prevent diversion. Likewise, Walgreens also failed to maintain effective controls against diversion from its pharmacy stores.

(1) Walgreens Delayed Developing a Suspicious Ordering System.

617. Though Walgreens had access to significant information about red flags due to its vertical integration with its stores, Walgreens failed to use available information to monitor and effectively prevent diversion.

618. At least as early as 1998, and perhaps as early as 1988, Walgreens began to utilize a series of formulas to identify orders that Walgreens deemed to be suspicious based on the orders' extraordinary size. These orders were listed on a report called the Suspicious Control Drug Order report.

619. Walgreens used two different formulas: one formula from (at least) 1998-2007 and one formula from March 2007 through 2012. These formulas were alike in that they each utilized an average number based on historical orders, applied a three times multiplier to that

base number, and then deemed certain orders which were greater than that number to be suspicious. Under the later formula, orders were only listed on the report as being suspicious if the orders exceeded the three times multiplier for two consecutive months in a given time period. Walgreens based this second formula on the DEA's Chemical Handler's Manual's order monitoring system for listed chemicals.

620. The first variation on this formula was in place until March 2007, even though the DEA warned Walgreens that the "formulation utilized by the firm for reporting suspicious ordering of controlled substances was insufficient," via a May 2006 Letter of Admonition. The Letter cited Walgreens for controlled substances violations at its Perrysburg, Ohio Distribution Center, but highlighted problems that went far beyond that particular facility.

621. The DEA also reminded Walgreens that its suspicious ordering "formula should be based on (size, pattern, frequency)," though Walgreens failed to even examine anything other than the size of an order. When Walgreens did update its program some ten months later, however, it still did not perform the size, pattern, and frequency analysis prescribed by the DEA, continuing to use another "three times" formula.

622. Walgreens did not perform any due diligence on the thousands of orders identified as "suspicious" on the Suspicious Control Drug Order reports, but instead shipped the orders without review.

623. Walgreens did not report the suspicious orders listed on the Suspicious Control Drug Order report until after the orders were already filled and shipped. The report was generated on a monthly, nationwide basis, directly contravening the regulatory requirement that suspicious orders be reported when discovered. 21 C.F.R. 1301.74(b). In some instances, months may have elapsed between an order's shipment and its subsequent reporting to the

DEA, given the requirement, described above, of two consecutive months of exceeding the three times multiplier to trigger reporting.

624. In September 2012, the DEA issued an immediate suspension order ("ISO") for one of Walgreens's three Schedule II distribution centers, finding Walgreens's distribution practices constituted an "imminent danger to the public health and safety" and were "inconsistent with the public interest." The DEA further found that Walgreens's Jupiter distribution center failed to comply with DEA regulations that required it to report to the DEA suspicious drug orders that Walgreens received from its retail pharmacies, resulting in at least tens of thousands of violations, particularly concerning massive volumes of prescription opiates.

(2) Walgreens Knew its After-the-Fact Excessive Purchase Reports Failed to Satisfy Its Obligations to Identify, Report, and Halt Suspicious Orders.

625. Walgreens knew its procedures were inadequate well before the 2012 ISO issued. In addition to the guidance described above, in 1988, the DEA specifically advised Walgreens that "[t]he submission of a monthly printout of after-the-fact sales does not relieve the registrant of the responsibility of reporting excessive or suspicious orders." The DEA further advised Walgreens that, while "[a]n electronic data system may provide the means and mechanism for complying with the regulations...the system is not complete until the data is carefully reviewed and monitored by the registrant."

626. Despite this instruction, there is no evidence that Walgreens ever took any action related to the Suspicious Control Drug Order report besides generating it and mailing it out. Walgreens has admitted that there is no evidence that Walgreens ever performed a due diligence review on any of the orders listed on the Suspicious Control Drug Order report before

shipment.

627. As described above, in May 2006, the DEA told Walgreens again that the formula Walgreens was using to identify suspicious orders for the Suspicious Control Drug Order reports was "insufficient" and "inadequate."

628. Moreover, in September 2007, three Walgreens's senior employees (Dwayne Pinon, Senior Attorney; James Van Overbake, Auditor; and Irene Lerin, Audit Manager) attended the DEA Office of Diversion Control's 13th Pharmaceutical Industry Conference in Houston, Texas. Michael Mapes, Chief, DEA, Regulatory Section, gave a presentation at this Conference relating to suspicious orders, which included the reminder that the CSA "requirement is to report suspicious orders, not suspicious sales after the fact." Participant notes from this meeting indicate that Mr. Mapes advised the audience not to "confuse suspicious order report with an excessive purchase report. They are two different things."

629. Similarly, handwritten notes on an internal document from July 2008 state that "DEA really wants us to validate orders and only report true suspicious orders or what was done to approve orders." They go on to state that "[j]ust reporting these orders is not good enough – need to document what happened."

630. Additionally, in November 2012, the Walgreens's Divisional Vice President of Pharmacy Services reported to Kermit Crawford, Walgreens's President of Pharmacy, Health and Wellness, his notes from meeting with the DEA about reporting suspicious orders, which included the note, "[i]f suspicious - you don't ship."

631. In a December 2008 Internal Audit of its Perrysburg Distribution Center, Walgreens admitted to systemic and longstanding failures in the systems surrounding DEA compliance, stating "In our opinion internal controls that ensure compliance with DEA

regulations at the Perrysburg DC require improvement. In addition, some of these issues pertain to all company DCs and should be addressed to avoid potential DEA sanctions."

632. The team that performed the Internal Audit recommended discussion continue across multiple departments company wide. In that respect, it makes clear that the failures described are systemic. However, the report states that the next meeting to address the problem would not occur for five months.

(3) Walgreens Lacked Meaningful Additional Systems to Address the Failures in Its System of After-the-Fact Reporting of Certain Orders.

633. Walgreens nominally employed additional procedures within its distribution centers; however, these systems did not address the failings of the Suspicious Control Drug Order reports. These distribution center systems were not designed to detect suspicious orders of controlled substances, but rather were designed to detect typos or errors in order entry by the stores. Walgreens admits that its Distribution Centers are "more akin to supply warehouses," are "not designed to be a backstop to pharmacists," and that they are not well "equipped to ensure compliance" or to "assist in combatting controlled substance abuse," and "do not have the ability to detect trends in local markets."

634. The Distribution Center ("DC") level procedures are documented in a 2006 Questionable Order Quantity policy, which had two facets: first, it instructed DC personnel to review orders and contact the pharmacy with questions regarding quantities. The policy did not mention reporting suspicious orders until 2010, when it was updated to state that the Corporate Office Internal Audit Department would handle suspicious store orders and inquiries. There is no evidence that the Internal Audit department had any involvement in reporting suspicious orders.

635. The second aspect of this DC level procedures required "pickers," the DC personnel who actually retrieved pill bottles off the shelves and placed them into totes for shipping, to look for "questionable" orders while picking.

636. The only review of the orders identified by the DC level procedures was calling the pharmacy to make sure the order had not been entered in error. Walgreens admitted this procedure was not intended to detect suspicious orders.

637. There is no evidence that any orders were ever reported as suspicious or halted as a result of Walgreens's distribution-center level policies. There is no evidence these procedures resulted in timely reporting of, due diligence on, or non-shipment of any order, including those listed as being "suspicious" on the Suspicious Control Drug Order reports.

638. Walgreens's documents effectively acknowledge that these were not true anti-diversion measures, and it recognized internally that it did not begin creating a suspicious order monitoring ["SOM"] system until March 2008. Specifically, in March 2008, Walgreens finally formed a five department "team" to "begin creating" a SOM program. The new SOM program was not piloted until more than a year later, in August 2009, and even then, the pilot included orders from just seven stores. Not until September 2010 would the program, implemented in pieces and phases, be rolled out chain-wide, and from that point it took several more years to fully implement.

639. Through 2012, Walgreens continued to populate the Suspicious Control Drug Order report with thousands of orders that exceeded Walgreens's "three times" test, showing that Walgreens's post-2009 SOM program did little to mitigate the extraordinary volume of controlled substances being shipped by Walgreens to its pharmacies.

(4) Even as it Rolled Out its New SOM Program, Walgreens Left Significant Gaps and Loopholes in Place and Failed to Report and Perform Due Diligence on Orders It Flagged.

640. Walgreens did not prioritize compliance when instituting its SOM system. MDL testimony from the Senior Director of the Walgreen's Pharmaceutical Integrity Department, which is charged with supervising Walgreens's SOM system, revealed that even as late as 2012, 2013, and 2014, Walgreens's viewed the SOM system as an inventory control mechanism rather than as a compliance control mechanism.

641. The SOM program had significant loopholes. For the first few years, the program did not include orders that Walgreens stores were also placing to outside vendors, like Defendants Cardinal and Amerisource Bergen., effectively permitting double-dipping.

642. The SOM system also allowed Walgreens's stores to transfer controlled substances between stores and did not review these transfers (known as "interstores") within the SOM program, so that these transfers were not factored into SOM analytics. Additionally, stores could also place ad hoc "PDQ" ("pretty darn quick") orders for controlled substances outside of their normal order days and outside of the SOM analysis and limits. Walgreens could even remove a store entirely from SOM review.

643. Starting in 2010, certain orders that exceeded store-based limits imposed by Walgreens's new SOM system were reduced to the store limit and shipped out. These orders were not reported to the DEA as suspicious, nor were they halted for review. The DEA found that Walgreens's policy of reducing and then filling and shipping suspicious orders without reporting them violated the law.

644. Walgreens's post-2009 SOM system flagged thousands of items per month as being suspicious. Internal Walgreens documents indicate that, in July 2011 alone, as many as

20,699 orders for controlled substances were "marked suspicious" by the new algorithm. However, very few of these orders received any review, and any review performed was nominal at best. Meanwhile, Walgreens failed to adequately staff the program and to train its employees regarding its requirements.

645. Walgreens cited two people as being primarily responsible for performing due diligence on suspicious orders in the 2009-2012 time period under the new SOM system. The first was a representative from the Loss Prevention department who said her department was "not equipped" to handle review and data analysis for the hundreds of pages of reports being compiled nationwide each week. The second was Barbara Martin, who estimated that she spent somewhere between one and three hours a week reviewing suspicious orders, reviewing only between 10 to 100 of the thousands of orders that were deemed suspicious under the new algorithm.

646. As a result of a DEA investigation, Walgreens formed the Pharmaceutical Integrity ("Rx Integrity") Team in 2012, purportedly to make sure that those types of failures did not continue. However, the group's true role was protecting Walgreens's Distribution Centers and stores from losing their DEA licenses. The effort was only for show. Walgreens never provided the Rx Integrity group the resources needed to achieve due diligence on the large number of orders identified by Walgreen's SOM program for the company's 5,000 plus stores.

647. In December 2012, the further enhanced SOM system flagged "14,000 items that the stores ordered across the chain that would have to be investigated" before they could be shipped.[301] Walgreens admitted that yet again it did not have sufficient resources to timely

[301] Supplemental and Amended Allegations to Be Added To "Short Form For Supplementing

review these orders. Walgreens noted that "[t]he DEA would view this as further failures of our internal processes, which could potentially result in additional pharmacies and distribution centers being subjected to regulatory actions and ultimately prohibited from handling controlled substances." At the time these 14,000 orders were flagged Walgreens Rx Integrity Team was comprised of fewer than five people.[302] Even at its height, Rx Integrity had only eleven employees. Instead of sufficiently staffing the SOM program, Walgreens recognized it had the ability to control its due diligence workload by increasing the stores' ceiling levels, and thereby reducing the number of orders that would hit that ceiling and result in a flag.

648. Yet, even in 2013, orders being flagged as suspicious for review before shipment were "a week old" before they made it to the review team, often "ha[d] already been shipped," and were not being reported.

649. Walgreens never equipped its distribution operations to monitor, report, and halt suspicious orders, or otherwise effectively prevent diversion. When it became clear Walgreens would need to devote significant resources to achieve compliance, Walgreens chose instead to cease controlled substance distribution all together.

650. Indeed, with respect to Walgreens's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. See Order [Denying Walgreen's Motion for Summary Judgment], MDL No. 2804, Doc. 2569 (N.D. Ohio Sept. 4, 2019).

Complaint And Amending Defendants And Jury Demand," *Co. of Trumbull, Ohio v. Purdue Pharma, L.P. et al. and Co. of Lake, Ohio v. Purdue Pharma L.P., et al.*, No. Doc. 2206-2, 73, N. 48 (WAGMDL000659270) (hereinafter "Lake Co. Complaint").

[302] *Id*. at 73, N. 49 (Polster Dep., at 24:3-15).

(5) Walgreens Failed to Put in Place Adequate Polices to Guard Against Diversion at the Pharmacy Level.

651. Although Walgreens purported to have in place "Good Faith Dispensing" ("GFD") Policies for many years, it failed to meaningful apply policies and procedures, or to train employees in its retail pharmacies on identifying and reporting potential diversion.

652. Despite knowing that prescribers could contribute to diversion, and having a separate and corresponding duty with respect to filling prescriptions, from at least 2006 through 2012, Walgreens's dispensing policies, which it titled "Good Faith Dispensing", or "GFD", explicitly instructed pharmacists who "receive[] a questionable prescription" or otherwise were "unable to dispense a prescription in good faith" to "contact the prescriber" and, if "confirm[ed]" as "valid" by the prescriber, to then "process the prescription as normal." Walgreens provided only vague criteria for suspicious circumstances, which became meaningless if a prescriber "confirm[ed]" the prescription as "valid," by calling the prescriber. Despite internally recognizing that "a prescriber of a controlled substance prescription [may be] involved in diversion", Walgreens's GFD policies continued to endorse calling the doctor as a greenlight to any "questionable" prescription.

653. In 2012, Walgreens finally removed the "process the prescription as normal" language from its formal GFD policies, admitting that under the law "it is not enough to get confirmation that the prescriber wrote the prescription." However, Walgreens still failed to ensure it complied with its duties.

654. Upon information and belief, Walgreens failed to adequately train its pharmacists and pharmacy technicians on how to prevent diversion, including what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when other suspicious circumstances are present.

655. Indeed, during the course of a 2009 DEA investigation into Walgreens dispensing noncompliance, Walgreens internally noted that it currently had "no training" for employees dispensing controlled substances. Meanwhile, Walgreens corporate officers turned a blind eye to these abuses. In fact, a Walgreens corporate attorney suggested, in reviewing the legitimacy of prescriptions coming from Florida, that "if these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance," underscoring Walgreens's attitude that profit outweighed compliance with the law or protecting public health.

656. Ultimately, in 2011, Walgreens and the DEA entered a Memorandum of Agreement regarding all "Walgreens . . . pharmacy locations registered with the DEA to dispense controlled substances," requiring Walgreens to implement significant nationwide controls lacking in its operations. Walgreen Co. was required to create a nationwide "compliance program to detect and prevent diversion of controlled substances as required by the … (CSA) and applicable DEA regulations." Pursuant to the MOA, the "program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor shopping and requests for early refills" as well as "routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA." Further, Walgreens was required to "implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations."

657. Walgreens would also make more promises in a 2013 MOA with the DEA, described further below, related to failures to that led to the ISOs described above.

658. Even after development and a relaunch of its GFD policy in response to settlements with the DEA, however, Walgreens "RxIntegrity" presentation focused on Walgreens "Market 25," but also assessing "average market" trends, reported that "pharmacists [were] not being too strict with GFD, nor [were] they losing volume."[303]

659. As with distribution, Walgreens failed to allocate appropriate resources to dispensing compliance and supervision. Walgreens has approximately 26,000 pharmacists, each of whom may receive as many as 400-500 prescriptions a day. In 2013, however, Walgreens internally reported that its District Managers and Pharmacy Supervisors were "challenged to get into the stores" and in a 90-day period, more than a thousand stores did not receive a visit from the managers or supervisors. These supervisory personnel were assigned a "high number of stores" and their time was consumed with "people processes, business planning, market and district meetings," such that supervision in store was being handled informally by "community leaders" who have "limited formal authority."

660. A Walgreens internal audit performed after the 2013 DEA settlement confirms that Walgreens's supervision and compliance failures continued. Among other failings, the audit team noted no formal monitoring program existed to confirm that pharmacies across the chain are complying with controlled substance documentation and retention requirements, no monitoring outside of the deficient "store walk program" existed to monitor target drug good faith dispensing requirements and no corporate reporting was being generated, and employees were failing to timely complete Good Faith Dispensing training, such that, at the time of the audit, over 35,000 employees had not completed their required training for that year.

[303] Market 25 consisted of Indiana, Kentucky, and West Virginia. Similar results reported for Market 3, Florida.

Management's response largely was to seek to incorporate additional compliance measures into the store walk procedure. However, documents from 2016 regarding monthly store compliance walks indicate that during the monthly "Compliance Walks" to "verify compliance … [with] regulatory requirements in… pharmacy areas," substantially no dispensing compliance supervision occurred, outside of ensuring the pharmacy was verifying the patient's address on five sample prescription fills.

661. Unsurprisingly, compliance with GFD and TD GFD has been poor. For example, in 2014 Walgreens discovered a pharmacist who failed to follow GFD for five to six months without being discovered by supervisors. In 2014, Rx Integrity noted dozens of stores dispensing opioids without performing the required checks. In certain cases, the pharmacists were unaware of the GFD procedures or had been told by supervisors to disregard them.

662. In 2015, Walgreens performed a "business continuity" audit of a random sample of approximately 2,400 pharmacies to determine whether Walgreens was "compliant with the policies/procedures put in place" regarding dispensing pursuant to Walgreens's agreement with the DEA. In Walgreens's own words, "Results were unfavorable." Fewer than 60% of stores were complying with TD GFD with respect to filled prescriptions, 1,160 stores did not have a single refused prescription, and an additional 1,182 stores had refused fewer than 25 prescriptions total in a nine-month period. Only 63 out of 2,400 pharmacies had refused 26 or more prescriptions during that same nine months in 2015.

(6) Walgreens Discouraged Outside Vendors from Exercising Their Own Oversight.

663. The "Big Three" wholesalers, Cardinal, McKesson, and AmerisourceBergen, gave deferential treatment to Retail Pharmacy Defendants. An internal Cardinal document for example, stresses that "certain chain pharmacies refuse to allow any sort of administrative

inspection by Cardinal or to make certifications" and that large, national chains can "take their billions upon billions of dollars in business to any wholesaler in the country."

664. Thus, for example, in 2008, Cardinal prepared talking points for a National Association of Chain Drug Stores (NACDS) Conference about its planned retail chain SOM program, making it clear that the program would "minimize the disruption" to retail chains and that they would "work together" with the pharmacies " to ensure that our Suspicious Order Monitoring program for retail chains does not interrupt" business. Cardinal also provided warnings to chain pharmacies, including Walgreens, that they were approaching thresholds so that the chains could avoid triggering SOM reporting and adjust ordering patterns by, for example, delaying orders or, more often, obtaining a threshold increase. Such "early warnings" were so helpful to Walgreens that as of 2012 Walgreens adopted the concept for its own SOM system for self-distribution, noting internally that by "flagging the stores at 75%," it could "avoid cutting/reducing orders and subsequently not have to report a SOM to the DEA."

665. In 2013, Walgreens entered a ten-year agreement with AmerisourceBergen Drug Company. The shift to AmerisourceBergen as its exclusive supplier prompted Cardinal to complain: "we bailed you guys out when you had your [DEA] issues."

666. By 2017, Walgreens accounted for 30% of AmerisourceBergen's revenue. AmerisourceBergen was similarly deferential, allowing Walgreens to "police their own orders and block any order to [AmerisourceBergen ("ABC")] that would exceed ABC's threshold thus triggering a suspicious order being sent to DEA from ABC. Additionally, when AmerisourceBergen received orders from Walgreens "outside the expected usage," Walgreens and AmerisourceBergen met to discuss adjusting thresholds or using "soft blocking." Contrary to DEA guidance and its own stated policy, AmerisourceBergen also shared the threshold limits

set by its "order monitoring program" with Walgreens, and also provided Walgreens with weekly SOM statistics. AmerisourceBergen generally would not take action on Walgreens orders that exceeded its thresholds without first talking to Walgreens.[304]

667. Walgreens also owns 26% of AmerisourceBergen's stock. In 2018, after a coalition of AmerisourceBergen shareholders sought greater transparency from its Board related to the "financial and reputational risks associated with the opioid crisis," Walgreens, together with other insiders, reportedly leveraged this position to defeat the proposal, which enjoyed majority support among the independent shareholders.

c) Walmart

668. Walmart is the largest private employer in the United States by far. It employs more than 1.5 million people. But for years, Walmart chose not to assign a single employee to design or operate a system to detect suspicious orders of controlled substances. Walmart chose to do nothing while hundreds of thousands of people were dying, and Walmart waited until 2014 to begin to take meaningful action. By that time, it was too late.

(1) Walmart Lacked A Suspicious Order Monitoring System for Most of the Relevant Time Period.

669. Like other Retail Pharmacy Defendants, Walmart self-distributed opioids to its retail stores. Specifically, Walmart operated registered distribution centers to supply its own pharmacies with controlled substances from the early 2000s until 2018 when it ceased self-distributing controlled substances. Walmart's conduct is particularly troubling given that it acted both as a self-distributing and dispensing pharmacy for such a long period of time.

[304] Rite Aid received similar accommodations from McKesson, which forwarded it dialed monitoring reports so that Rite Aid could "let [McKesson know] if it needed to make any adjustments to its thresholds. Lake Co. Complaint, *supra* note 301 at 80, N. 52 (MCKMDL00646634).

670. Prior to 2011, Walmart had not designed any formal system to identify suspicious orders of controlled substances and, therefore, utterly failed to meet its statutory obligations.

671. Walmart has claimed that its hourly employees and associates—who were also responsible for filling orders at Walmart Distribution Centers—monitored the orders they were filling for unusual size, pattern, and frequency. Typically, this "review" involved between 700 and 800 orders a day. Walmart has also claimed that these hourly associates were instructed to alert a supervisor if an order appeared unusual based on their experience and memory.

672. Upon information and belief, Walmart can produce no written evidence of any such instructions to Walmart associates, no evidence of any training that would be required to implement such a procedure, or anyone actually being alerted about an unusual order or performing any follow up inquiry.

673. Walmart failed to provide any guidance to the associates as to what constitutes a "suspicious" order. Instead, Walmart emphasized its associates' subjective judgment based on their "knowledge and experience" as distribution center employees. There is no evidence that any Walmart employee ever flagged an order as suspicious prior to 2011.

674. Walmart purportedly implemented a "monitoring program" that would identify suspicious orders of controlled substances in 2011. This system purportedly was in place until 2015.

675. Walmart's monitoring program was insufficient to identify suspicious orders of controlled substances. The program flagged only very large orders of controlled substances. Specifically, it flagged weekly orders for controlled substances of 50 bottles (5,000 dosage units) or more and orders or more than 20 bottles (2,000 dosage units) that were 30% higher

than a rolling four-week average for that item. Orders under 2,000 units per week were never flagged, meaning that a pharmacy could order 8,000 units per month without ever being flagged. Moreover, that meant that even if an order was more than 30% greater than the four-week average, it could not draw an alert unless it also was more than 20 bottles.

676. Under this system, an alert did not mean Walmart would report the order or halt it pending necessary due diligence. To the contrary, upon information and belief, Walmart never reported an order flagged by its monitoring program to the DEA as suspicious. In addition, rather than halting the order, Walmart simply cut the order to the amount of the 50 bottles threshold and shipped it. Walmart never reported cut orders to the DEA. Although information regarding flagged orders was available and sent daily to Walmart's headquarters in Arkansas (the "Home Office"), no one from the Home Office ever reviewed or took any action regarding flagged orders.

677. This practice continued until mid-2012, when Walmart implemented "hard limits" on opioid orders. Under this approach, weekly orders of Oxycodone 30mg ("Oxy 30") were automatically reduced to 20 bottles. Still, Walmart failed to report the orders to the DEA.

678. During this time period, Walmart also monitored weekly orders of other controlled substances in quantities of more than 20 bottles. Specifically, an "Over 20 Report" was provided to the Home Office in the morning and if nothing was done by mid-afternoon, the orders were filled and shipped. Upon information and belief, there is no evidence of any order in fact being held or reviewed pursuant to this practice.

679. Further, cutting the order did not mean that the Walmart pharmacy would not receive the full supply. Walmart pharmacies also purchased opioids from outside suppliers, including McKesson and AmerisourceBergen. Pharmacies could place another order with these

outside vendors to make up the difference, or in some cases, have orders fulfilled by both Walmart and a third-party distributor at the same time. Thus, even though Walmart had the ability to monitor such orders, it chose not to, which allowed its pharmacies to surpass its already high thresholds by simply ordering drugs from a third party.

680. Walmart knew that its monitoring program was insufficient to fulfill its obligations to prevent diversion. For example, in 2013, Walmart acknowledged in an internal presentation that it had not yet designed a compliant system for suspicious order identification, monitoring, and reporting. It was not until 2014 that Walmart's written policies and procedures required orders of interest to be held and investigated.

(2) Walmart's "Enhanced" Monitoring Program Fails to Remedy Deficiencies in its Monitoring Program.

681. In 2015, Walmart enhanced its suspicious order monitoring policy by implementing store-specific thresholds. Upon information and belief, it based these thresholds on the standard deviation of a specific pharmacy's order history for each controlled substance. The thresholds also included minimum amounts, below which no orders were flagged under any circumstance, regardless of pattern or frequency.

682. Walmart's corporate designee, testifying on its behalf in the MDL, conceded that thresholds were set for business purposes, not for the purpose of "main[taining] of effective controls against diversion . . . into other than legitimate . . . channels . . . ." 21 U.S.C.A. § 823(a)(1), (b)(1). Further, for almost all Walmart pharmacies, this minimum was set at 2,000 dosage units per week (or 8,000 dosage units per month).

683. With respect to Walmart's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of Walmart's suspicious order monitoring efforts in that

litigation. *See* Opinion and Order Denying Walmart's Motion for Summary Judgment, MDL No. 2804, Doc. 3102 (N.D. Ohio Jan. 27, 2020). In doing so, it "noted[d] the record evidence suggests obvious deficiencies that a layperson could plainly recognize." *Id.* at 4, n.12.

d) Rite Aid

684. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third largest in the United States, with annual revenue of more than $21 billion.

(1) Rite Aid Failed to Maintain Effective Controls Against Diversion at the Wholesale Level.

685. Rite Aid distributed Schedule III ("CIIIs") controlled substances (e.g., hydrocodone combination products) to its own Rite Aid stores until late 2014. Rite Aid distributed through its Perryman Distribution Center (Rite Aid of Maryland, Inc., d/b/a Rite Aid Mid-Atlantic Customer Support Center) and its Liverpool Distribution Center (Eckerd Corporation d/b/a Rite Aid Liverpool Distribution Center), both DEA registrants.

686. Rite Aid's controlled substance distribution process was fairly simple. Rite Aid used a computerized "auto-replenishment system" (ARS) through which individual Rite Aid pharmacies would generate orders that were sent to the distribution center (DC). This ARS relied directly on dispensing data and the dispensing patterns of individual Rite Aid stores. If the ARS generated an order that was above Rite Aid's universal 5,000 dosage-unit (DU) threshold, the DC employees filling the order were supposed to manually recognize that the order was above threshold. If they did observe an order over threshold, the only "review" of the order was an attempt to call the pharmacy that placed the order to verify the order amount was correct (i.e., that it was not a "fat-finger" error). If the pharmacy confirmed that the above-threshold order

amount was correct, or if the DC simply could not contact the pharmacy, the order was cut to the threshold and shipped. All the above-threshold orders were supposed to be maintained on a handwritten log containing only basic information about the order.

687. After the orders had shipped, Rite Aid monitored its inventory through its Navicase/Naviscript system. The Rite Aid Asset Protection Department used "key performance indicators" (KPIs) to analyze data about ordering from the Rite Aid stores to identify diversion through theft. Yet, as numerous Rite Aid witnesses have testified, Rite Aid did not use the Navicase/Naviscript system to identify—much less report—suspicious orders. Furthermore, assuming that the Navicase/Naviscript could identify suspicious orders, the Navicase/Naviscript data analysis only took place after shipment.

688. Rite Aid maintained a small, inadequate list of suspicious prescribers but did not make any efforts to identify or report any suspicious orders from stores Rite Aid knew were dispensing prescriptions for those suspicious prescribers. Further, given that orders would have already shipped, Rite Aid did not incorporate "suspicious prescriber" information that it may have collected in determining whether an order from any location was suspicious.

689. Ultimately, Rite Aid's distribution system made it nearly impossible for any order to be identified, much less reported, as suspicious. As a result of the company's policies and procedures, Rite Aid did not – and indeed, could not – identify what was unusual because all Rite Aid DCs had a static, blanket threshold for all Rite Aid stores above which Rite Aid would cut the order. The threshold, which never changed, was set at 5,000 DUs, per national drug code (NDC), per order (although Rite Aid does not know why it was set at 5,000 DUs). Rite Aid stores typically ordered once per week, but some stores ordered twice per week and others ordered every two weeks. That means that at its lowest, the Rite Aid threshold was 10,000 DUs

per month, per store and at its highest it was 40,000 DUs per month, per store.

690. Despite the extremely high threshold amount, Rite Aid did not have a procedure that required anyone to report an order that came in over the universal threshold as suspicious. Instead, DC employees would "cut" the order down to the threshold and then ship the order. Rite Aid did no due diligence on orders that came in over the blanket threshold. An overwhelming number of the "cut" orders, if not all, were not reported to the DEA until after the fact, if at all.

691. Rite Aid also had little to no records about past order history to determine if an order was suspicious. The Perryman DC kept what was called a "Threshold Log," which contained in hard copy only basic information about orders that exceed the threshold: date of order, store number, item number, item description, quantity ordered, allowable quantity, and the reason for the allowable quantity. But, any use of the log to potentially identify suspicious orders was only done sporadically and after the above-threshold orders were cut and shipped.

692. Additionally, Rite Aid placed the responsibility to identify orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency on employees whom the DEA coordinator at the Rite Aid's distribution center testified were not able to actually do so.

693. Recognizing its failure to have a system, Rite Aid did begin to develop a suspicious order monitoring system for the first time in 2013. In the end, however, Rite Aid never adopted the new SOM system because it stopped distributing controlled substances before this system could be implemented.

694. With respect to Rite Aid's suspicious order monitoring system for its wholesale distribution, the MDL Court has denied a motion for summary judgment contesting the evidence regarding the inadequacy of its SOM system in that litigation. *See* Opinion and Order [Denying

Rite Aid's Motion for Summary Judgment], MDL No. 2804, Doc. 3100, 2020 WL 425940 (N.D. Ohio Jan. 27, 2020).

(2) Rite Aid Conspired with McKesson to Avoid Scrutiny of Outside Vendor Orders and Adjust or avoid Thresholds.

695. Rite Aid conspired with McKesson to avoid suspicious order reporting. McKesson was Rite Aid's exclusive wholesaler for Schedule II controlled substances, including opioids, during the relevant time period. Rite Aid also ordered CIIIs from McKesson during the relevant time period. Rite Aid ordered CIIIs from McKesson not only when it stopped self-distributing in late 2014, but McKesson also supplemented Rite Aid stores' supply of Schedule III controlled substances during the period when Rite Aid self-distributed controlled substances.

696. McKesson provided Rite Aid with notification of stores hitting McKesson's thresholds and regularly granted threshold increases without conducting any due diligence. For example, when a McKesson report revealed a number of Rite Aid stores were at 90% of their threshold and about to be flagged, McKesson offered to—and did—increase the thresholds for all Rite Aid locations by 50%. McKesson also forwarded daily monitoring reports to Rite Aid so that Rite Aid could "let [McKesson] know" if McKesson "need[ed] to make any adjustments to current thresholds."

697. On one occasion, Rite Aid noted that over 10% of its stores came close to being blocked, and McKesson simply asked Rite Aid how high it wanted the thresholds increased. McKesson also prompted Rite Aid to delay its orders until the next month in order to avoid hitting monthly thresholds when they were getting close.

698. A striking example of Rite Aid's collaboration with McKesson to avoid suspicious order reporting occurred in Ohio, involving customers of Dr. Adolph Harper. Dr.

Harper, now in prison, is an ob-gyn who prescribed opioids at shocking volumes and doses to patients who included large numbers of men, who frequented Rite Aid stores to fill their prescriptions. Rite Aid worked with McKesson to ensure an increase in the amount of opioids Rite Aid could order from McKesson specifically to meet the illegitimate demand from Dr. Harper. Neither Rite Aid nor McKesson reported any of these orders as suspicious.

699. Rite Aid allowed its stores to order from McKesson without any restriction and failed to take those orders into account in Rite Aid's self-distribution SOM system, negating any constraints from Rite Aid's even limited internal controls.

3. The National Retail Pharmacies' Put Profits Before Safety.

a) National Retail Pharmacies Employed Performance Metrics That Inevitably Led To Diversion

700. Not only did the Chain Pharmacies lack (and fail to implement) adequate policies and procedures to guard against diversion, but CVS, Rite Aid, and Walgreens, and upon information and belief, the other Chain Pharmacies compounded this problem by implementing performance metrics and prescription quotas for retail stores that contributed to supplying of a black market.

701. In connection with the DEA's investigations described above, the DEA found evidence that Walgreens had a corporate policy encouraging increased sales of oxycodone.[305] As the DEA's September 2012 Order to Show Cause and Immediate Suspension of Registration explains:

> In July 2010, Walgreens's corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions

[305] Lake Co. Complaint, *supra* note 301 at 118, N. 67 (WAGMDL00387654-666 (September 13, 2012 Order to Show Cause and Immediate Suspension of Registration to Walgreens's Jupiter, Florida Distribution Center)).

> dispensed in June. The spreadsheet was sent to Walgreens's market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce." A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "busiest store in Florida" was filling almost 18 oxycodone prescriptions per day, yet "We also have stores doing about 1 a day. Are we turning away good customers?"

702. In 2011, a Walgreens project to "Increase Rx Sales and prescription Counts" instructed pharmacies to "improve C2 business" —i.e. dispense more Schedule 2 controlled substances. This focus on increasing controlled substance dispensing—including opioids—continued even after the DEA investigation and $80 million fine.

703. In 2014, the Walgreens RX Integrity department created a "Pharmacist Controlled Substance Dispensing Opportunities" tool to "identify pharmacists that are dispensing a low rate of controlled substances," and help pharmacists "feel more comfortable in filling controlled substances," specifically focusing on pharmacists dispensing low rates of opioids like "hydromorphone, oxycodone, methadone… hydrocodone," and the cocktail drugs comprising the rest of the "holy trinity" of abuse, such as "carisoprodol… [and] alprazolam."

704. Walgreens also had a bonus program that factored prescription volume into bonus calculations and served as an incentive for pharmacies and pharmacy technicians to ignore the "red flags" of diversion. The corporate push for speed (or volume) deterred pharmacists from taking the time to properly examine the prescriptions before them and exercising their corresponding responsibility to prevent diversion.

705. Indeed, Walgreens had a tool, the "PhLOmometer" that tracked the time to fill a prescription. A March 2013 memo confirms that volume targets included controlled substances as late as 2013 and even after the adopting of the GFD policy. Specifically, the memo states, as the response to an "[a]nticipated question" that "GFD concerns doesn't relieve you from trying

to attain the numbers that have been set for you." When considering high schedule 2 dispensing at a particular pharmacy in New Jersey in 2012, as the opiate crisis raged, the pharmacy supervisor pushed back against any attempt to reduce supply of oxycodone, focusing on the impact the reduction would make on filled prescriptions and "the bonus tied to" one pharmacy employee.

706. Only as part of its 2013 settlement with the DEA did Walgreens agree to exclude controlled substances calculations from bonus calculations from 2014 forward. This resulted in a 21% reduction in the number of stores purchasing the 80mg OxyContin – evidence that a minimal effort to implement common sense controls had a tangible impact on sales of the most potent controlled substances (although that reduction did not last, as described above, and Walgreens's volume by 2014 had increased again).

707. CVS used performance metrics related to its own profits, which would rely, in part, upon the number of prescriptions dispensed. By 2010, CVS had implemented performance metrics that remain publicly available online. CVS's metrics system lacked any measurement for pharmacy accuracy or customer safety. They did, however, prioritize speed and volume, including by requiring pharmacists to meet wait- or fill-time expectations. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. Opioid prescriptions were even included in the volume goals until 2013. Even in 2020, pharmacists described CVS as the "most aggressive chain in imposing performance metrics."[306]

708. This pressure and focus on profits has necessarily deterred pharmacies from

[306] Ellen Gabler, How Chaos at Pharmacies Is Putting Patients at Risk, New York Times, (Jan. 31, 2020), https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html.

carrying out their obligations to report and decline to fill suspicious prescriptions and to exercise due care in ascertaining whether a prescription is legitimate.

709. In 2013, the National Association of Boards of Pharmacy (NABP), passed a resolution which stated that "performance metrics, which measure the speed and efficiency of prescription work flow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift, may distract pharmacists and impair professional judgment" and "the practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."[307]

710. Still, according to a 2016 investigation by the Chicago Tribune, as chain pharmacies increasingly promote quick service, "pharmacists frequently race through legally required drug safety reviews — or skip them altogether," missing dangerous drug combinations in the process.[308]

711. In March 2020, journalists also revealed that Walmart not only ignored reports of suspicious activity from pharmacists concerned that they were filling prescriptions for pill mills, but the company considered these pharmacists' focus misdirected. One internal email, reviewed by ProPublica, showed that in response to a question from a regional manager in 2015

[307] NAPB, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/newsroom/news/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution-109-7-13/

[308] Sam Roe, Ray Long, and Karisa King, Contract Reporters, Pharmacies Miss Half of Dangerous Drug Combinations, Dec. 15, 2016, https://www.chicagotribune.com/investigations/ct-drug-interactions-pharmacy-met-20161214-story.html.

about documenting pharmacists' concerns about doctors believed to be operating pill mills, Walmart's director of Health and Wellness Practice Compliance, Brad Nelson, wrote that "We have not invested a great amount of effort in doing analysis on the data since the agreement [requiring such reporting] is virtually over. Driving sales and patient awareness is a far better use of our Market Directors and Market manager's time.[309]

b) National Retail Pharmacy Defendants Worked Together to Increase Their Profits and Lobbied Against Restrictions on Opioid Use and DEA Enforcement.

712. Walgreens and the other Defendants recognized the importance of controlling and influencing trade groups such as the NACDS in the context of influencing policy related to opioid drug abuse and diversion. The efforts taken by the NACDS and other trade groups on behalf of Defendants were so important to their bottom line that Defendants spared no expense in supporting such groups. Walgreens took a particularly aggressive view of this mutually beneficial relationship, at times, being its top donor across the country.

713. NACDS worked with the HDA, the Alliance to Prevent the Abuse of Medicines ("APAM"), and the PCF to support the Marino Blackburn Bill, also known as S.483 or the "Marino Bill". NACDS and Defendants intended the Marino Bill to "tie the hands" of the DEA to "actively and aggressively address diversion and compliance with the CSA." NACDS worked together with others in the opioid supply chain to influence the language in the bill to make it most favorable for them and more restrictive on the DEA. Notably, masking the influence of industry, when the APAM was asked to sign on to a 2014 letter of support it was

[309] Jesse Eisinger and James Bandler, Walmart Was Almost Charged Criminally Over Opioids. Trump Appointees Killed the Indictment., ProPublica, (March 25, 2020), https://www.propublica.org/article/walmart-was-almost-charged-criminally-over-opioids-trump-appointees-killed-the-indictment.

"signed by the Alliance, not the individual members." The final letter that was sent to Senators Hatch and Whitehouse was signed by the members of the Pain Care Forum as well as the Alliance, the NACDS, American Academy of Pain Management, and U.S. Pain Foundation.

714. The Marino Bill effectively removed the DEA's ability to issue immediate suspension orders regarding manufacturer or distributor registrations. The Marino Bill permitted a non-compliant registrant an opportunity to cure its noncompliance before the DEA could take enforcement action and changed the standard upon which revocation occurred. In the midst of a growing opioid crisis, the Marino Bill removed the most effective deterrent and constrained DEA enforcement actions.

715. In August of 2011, NACDS worked with others on a joint letter opposing DEA fee increases for registrants that were intended to fund the "hir[ing of] more agents and do[ing] more inspections."

716. HDA's Crisis Handbook, developed in 2013, was a direct response to the "threats" perceived by HDA's members and affiliates, including Defendants, to their bottom line: profits derived from the distribution and sale of prescription opioids.[310] Defendants did, and continue to, rely on and employ the strategies discussed in the Crisis Playbook. Curiously, there are no slides on how best HDA and its members, including Defendants, might work to curb the crisis that is the opioid epidemic.

717. In 2016, the NACDS Policy Council discussed ongoing efforts to shape opioid legislation, including their success in removing a requirement that pharmacists have to check their state drug monitoring program before filling controlled prescriptions.[311] NACDS also

[310] Lake Co. Complaint, *supra* note 301 at 130, N. 86 (ABDCMDL00278063).
[311] *Id*. at 132, N. 87 (WAGMDL00605718 (including Walgreens & Walmart)).

fought regulatory efforts to require Defendants to use available dispensing related data and red flags to prevent diversion, opposing what it described as "recent DEA actions in which DEA is expecting pharmacists to be enforcement agents with respect to prescriptions for pain medications."

718. NACDS and HDA sought to slow down and impede DEA enforcement activities by requiring the DEA to "work with the [Food and Drug Administration] FDA on all drug diversion issues," ostensibly on the grounds that the DEA's diversion enforcement activities – including "clos[ing] drug distribution centers and pharmacies" and "actions against pharmacies" – were harmful in "leading to patients not being able to receive their medications." This purported concern, however, was industry code for impediments to sales.

c) Retail Pharmacies Worked With Manufacturing Defendants to Promote Opioids and Bolster Their Profits at the Expense of Communities.

719. Retail Pharmacy Defendants also worked in concert with opioid manufacturers to ensure that the false messaging surrounding the treatment of pain and the true addictive nature of opioids was consistent and geared to increase profits for all stakeholders.

720. For example, as early as 2001, CVS worked closely with Purdue and its un-branded marketing arm, Partners Against Pain ("PAP") to "fight back" against allegations (later proved to be true) that Purdue's Oxycontin was being abused at alarming rates. It was Purdue's Partners Against Pain website that Purdue, and its "Partners" including CVS, utilized to make the claims that the risk of addiction associated with Oxycontin was very small.

721. Purdue worked together with CVS to ensure that CVS's own pharmacists were trained by Purdue on many of the misleading marketing messages that would later form the basis for a 2007 criminal guilty plea and $600 million fine between Purdue and the Department

of Justice for misleading regulators, doctors, and patients about Oxycontin's risk of addiction and its potential for abuse. CVS's ties to PAP were so deep that CVS even went so far as to put CVS's own logo communications from its "partner".

722. CVS was so eager to ally itself with Purdue and its partners that it solicited Purdue for its participation in co-hosting Continuing Education programs for healthcare providers and pharmacists regarding training on diversion of prescription opioids.

723. CVS's role was not limited to expanding the market for prescription opioids. CVS worked hard to ensure that demand for prescription opioids was not only sustained but multiplied. It did so through its marketing, advertising and promotional efforts both on its own and in concert with other stakeholders.

724. CVS worked with Defendant Endo to increase patient adherence to continuing their use of opioids. In fact, CVS played such an important part in the promotion of Endo's Opana ER that it was included as having a crucial role in carrying out one of key sales tactics included in Endo's 2012 Business Plan.

725. Through a company called Catalina Health ("Catalina"), Endo was able to target Oxycontin patients in areas where Opana ER, a highly abused opioid manufactured by Endo, had preferred formulary status. Catalina in turn worked to create a brand loyalty program that kept new patients on their opioids. CVS, through its pharmacy retention programs, sent letters to the patients' homes to encourage them to stay on Opana – even though prolonged use of opioids increases the risk of addiction, and even though patients in pain presumably need no reminder to continue to take their pain medications. CVS formalized its agreement to promote, market and advertise Endo's opioid products via its "CVS Carecheck Plus Patient Education Service".

726. Similarly, CVS contracted with manufacturers like Endo to prepare and disseminate materials promoting Opana ER nationwide.

727. CVS likewise helped Actavis promote its opioids by participating with Cardinal's Marketing and Business Development team in programs designed to offer rebates and off-invoice discounts on products, with the aim being to "move [] product."

728. CVS made at least one pitch to Insys to help sell its incredibly potent opioid, Subsys, a liquid form of fentanyl.

729. Working with Purdue as early as 2001, Walgreens played a pivotal role in expanding the market and ensuring the demand and supply for prescription opioids would grow to exponentially. Purdue was particularly interested in using what Walgreens described to Purdue as its Regional Level Market Programs to educate pharmacists and patients on the benefits of Purdue's OxyContin. In fact, Purdue leveraged its relationship with Walgreens and their mutually beneficial goal of growing the opioid business to ensure that Purdue had input into Walgreens "corporate guidelines" to which Walgreens pharmacists were "expected to follow" when it came to the dispensing of prescription opioids.

730. Walgreens also used its corporate oversight abilities to identify stores it believed were not filling enough oxycodone to make sure they weren't "turning away good customers" and encouraging stores to utilize continuing education created by opioid manufacturers to inform their decisions regarding dispensing.

731. Starting in at least 1999, Purdue sponsored Walgreens's Pharmacy continuing education programs designed to encourage stores to "get on the Pro Pain Management Band Wagon." Purdue was thrilled with the response and assistance it received from Walgreens when Purdue presented on "Pain Management for the Pharmacist." At the beginning of each Purdue

sponsored meeting, a Walgreens pharmacist made a presentation on his store and the program implemented. His store actively advertised to area doctors and patients that they were a "full service" pain management pharmacy. This service included providing a list to physicians' offices of all CIIs they had in stock (and they had everything), accepting "verbal orders" for Class II analgesics prior to presentation of the original prescription at the store to decrease "waiting time", allowing partial fills on CII prescriptions in terminal patients, and accepting after hours "emergency CII prescriptions" without a hassle. Purdue praised the pharmacist's actions as "fantastic".

732. Walgreens's use of pro-opioid continuing education continued as the opioids crisis grew. For example, Walgreens's Market Director of Pharmacy Operations recommended that Walgreens District Managers and Pharmacy Supervisors attend a continuing education program titled ""The Pharmacists' Role in Pain Management: A Legal Perspective," which was available on-line at RxSchool.com. This program was one in a long line of pharmacist "education" programs, or CEs, that opioid manufacturer Purdue developed as part of its strategy to disseminate "a new school of thought" about opioids. Through these programs, Purdue and the Retail Pharmacy Defendants disseminated fraudulent information that redefined the red flags of abuse or diversion in an effort to correct pharmacists' "misunderstanding" about pain patients and the practice of pain management. Purdue took what it called an "aggressive role" in the education of Walgreens's and other pharmacists on pain management issues.

733. Walgreens's Market Director of Pharmacy Operations also recommended a second continuing education program titled "Navigating the Management of Chronic Pain: A Pharmacist's Guide," which Defendant Endo sponsored. One of the presenters was Kenneth Jackson, a co-author of the CE program titled "Use of Opioids in Chronic Noncancer Pain,"

which was sponsored by Purdue. Released in April 2000, it was designed to eliminate "misconceptions about addiction, tolerance and dependence" and contained many of the same messages as the pharmacist guide he authored.

734. Walgreens also presented the video, The Pharmacist's Role in Pain Management - A Legal Perspective at mandatory meetings for pharmacy managers. This continuing education program ("CE") was also sponsored by Purdue, was similar to the earlier presentations, and was further disseminated to Walgreens pharmacists in June 2011. Released in 2009, the program was presented by Jennifer Bolen, JD. Ms. Bolen was a frequent speaker for Purdue and other opioid manufacturers, served as Special Counsel for the American Academy of Pain Medicine (a known front group for opioid manufactures).

735. The meeting caused Walgreens pharmacists who had stopped filling prescriptions for controlled substances to start filling them again.

736. Rite Aid likewise helped to expand the market and increase the demand for prescription opioids by working in concert with manufacturers like Purdue. Capitalizing on Rite Aid's reach, Purdue worked with Rite Aid as early as 2001 to promote its highly addictive, OxyContin. Purdue conducted pharmacy programs with Rite Aid pharmacists to provide an "overview" of pain management. Both Purdue and Rite Aid recognized the importance of a chain pharmacy and pharmacists in the efforts to expand and sustain the demand for prescription opioids.

4. Multiple Enforcement Actions Against the National Retail Pharmacies Confirms their Compliance Failures

737. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal law and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly

penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

738. Numerous state and federal prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this complaint do not attempt to identify all these prosecutions, and the information below is merely by way of example.

a) CVS

739. CVS is a repeat offender and recidivist: the company has paid fines totaling over $40 million as the result of a series of investigations by the DEA and the United States Department of Justice ("DOJ"). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

740. Confirming its systemic failures to implement and adhere to adequate controls against diversion, CVS has repeatedly faced enforcement actions. In May 2020, CVS's Omnicare subsidiary agreed to pay a $15.3 million civil penalty as part of a settlement with the DEA resolving allegations that it improperly dispensed opioids and other controlled substances to long-term care facilities without a valid prescription.

741. In March 2019, CVS Pharmacy, Inc. (including all of its relevant subsidiaries and affiliates) entered into a $535,000 settlement with the U.S. Attorney's Office for the District of Rhode Island, acting on behalf of the United States, and the DEA's Providence Office. In connection with the settlement, a DEA agent stated: "Pharmacies put patients at risk

when they dispense Schedule II narcotics, which have the highest potential for abuse, without a valid and legal prescription.[312]

742. In August 2018, CVS paid $1 million to resolve allegations that CVS pharmacies throughout the Northern District of Alabama violated record-keeping requirements under the CSA and its implementing regulations, the largest civil fine paid in Alabama by a DEA registrant.

743. In June 2018, CVS paid $1.5 million to resolve allegations that CVS pharmacies in Long Island, New York failed to timely report the loss or theft of controlled substances, including hydrocodone, recognized as one of the most commonly diverted controlled substances.

744. In July 2017, CVS entered into a $5 million settlement with the U.S. Attorney's Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances. The fine was preceded by numerous others throughout the country.

745. In February 2016, CVS paid $8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

746. In October 2016, CVS paid $600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

747. In September 2016, CVS entered into a $795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the

[312] Press Release: CVS to pay $535,000 for filling invalid prescriptions, U.S. Drug Enforcement Administration (Apr. 16, 2019), https://www.dea.gov/press-releases/2019/04/16/cvs-pay-535000-filling-invalid-prescriptions.

state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

748. In June 2016, CVS agreed to pay the DOJ $3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

749. In August 2015, CVS entered into a $450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

750. In May 2015, CVS agreed to pay a $22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need."

751. In September 2014, CVS agreed to pay $1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

752. In 2013, CVS agreed to pay $11 million to resolve allegations it violated the

CSA and related federal regulations at its retail stores in Oklahoma and elsewhere by: (1) creating and using "dummy" DEA registration numbers on dispensing records, including records provided to state prescription drug monitoring programs; (2) filling prescriptions from prescribers who lacked current or valid DEA numbers; and (3) substituting the DEA number of non-prescribing practitioners for the DEA numbers of prescribers on prescription records.

753. In August 2013, CVS was fined $350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

754. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

b) Walgreens

755. Walgreens also has been penalized for serious and flagrant violations of the CSA. Indeed, Walgreens agreed to the largest settlement in DEA history at the time—$80 million—to resolve allegations that it committed an unprecedented number of recordkeeping and dispensing violations of the CSA, including negligently allowing controlled substances such as oxycodone and other prescription painkillers to be diverted for abuse and illegal black market sales.

756. The settlement resolved investigations into and allegations of CSA violations in Florida, New York, Michigan, and Colorado that resulted in the diversion of millions of opioids into illicit channels.

757. Walgreens's Florida operations at issue in this settlement highlight its egregious conduct regarding diversion of prescription opioids. Walgreens' Florida pharmacies each

allegedly ordered more than one million dosage units of oxycodone in 2011—more than ten times the average amount.

758. They increased their orders over time, in some cases as much as 600% in the space of just two years, including, for example, supplying a town of 3,000 with 285,800 orders of oxycodone in a one-month period.

759. Defendant Walgreens' settlement with the DEA stemmed from the DEA's investigation into Walgreens' distribution center in Jupiter, Florida, which was responsible for significant opioid diversion in Florida. According to the Order to Show Cause, Defendant Walgreens' corporate headquarters pushed to increase the number of oxycodone sales to Walgreens' Florida pharmacies, and provided bonuses for pharmacy employees based on number of prescriptions filled at the pharmacy in an effort to increase oxycodone sales. In July 2010, Defendant Walgreens ranked all of its Florida stores by number of oxycodone prescriptions dispensed in June of that year and found that the highest-ranking store in oxycodone sales sold almost 18 oxycodone prescriptions per day. All of these prescriptions were filled by the Jupiter Center.

760. Walgreens has also settled with a number of state attorneys general, including West Virginia ($575,000) and Massachusetts ($200,000).

761. The Massachusetts Attorney General's Medicaid Fraud Division found that, from 2010 through most of 2015, multiple Walgreens stores across the state failed to monitor the opioid use of some Medicaid patients who were considered high-risk.

762. In January 2017, an investigation by the Massachusetts Attorney General found that some Walgreens pharmacies failed to monitor patients' drug use patterns and didn't use sound professional judgment when dispensing opioids and other controlled substances—despite

the context of soaring overdose deaths in Massachusetts. Walgreens agreed to pay $200,000 and follow certain procedures for dispensing opioids.

c) Walmart

763. In addition to the actions described above against Walmart, a prosecution against a Virginia prescriber revealed failures at Walmart pharmacies from 2007 to 2012. A Decision and Order in that case revealed that a Walmart pharmacy would fill prescriptions pursuant to a telephone message from a staff member of the prescriber, purportedly on behalf of the prescriber even though the staff member failed to provide the prescriber's DEA number.[313] By mid-November 2008, three Walmart pharmacies had dispensed more than 200 hydrocodone prescriptions and refills on behalf of the prescriber. In 2012, the prescriber learned that someone was fraudulently using his DEA number. He called a Walmart pharmacy regarding refill requests faxed from his office and advised "that somebody was fraudulently using [his] DEA number."[314] Although he asked that his DEA number be blocked, the same pharmacy filled an additional two prescriptions on his behalf after this alert. Although Walmart did not face sanctions for its conduct, the Opinion and Order described "the fact that prescriptions which were missing [the] Respondent's DEA number were routinely filled notwithstanding that they were facially invalid," and "that the prescriptions were for hydrocodone in quantities and dosings that were clearly outside the scope of what is usually prescribed by podiatrists" as "deeply disturbing."[315]

764. Walmart paid a $637,000 fine to settle an action by federal prosecutors against

[313] DOJ, DEA, Docket No. 15-26, [FR Doc. No. 2017-13158] Peter F. Kelly, D.P.M.; Decision and Order, https://www.deadiversion.usdoj.gov/fed_regs/actions/2017/fr0623.htm.
[314] *Id.*
[315] *Id.*

five Walmart and Sam's Club Pharmacies in Texas, alleging that they failed to keep records required to help prevent diversion of controlled substances as required by the CSA. Specifically, "accountability audits did not match the drugs on hand, revealing major overages and shortages in the accountability of controlled substances, and there were missing invoices for controlled substances all in violation of the CSA."[316] A U.S. Attorney further explained that "[b]ecause of the pharmacies' lack of proper record keeping, a variety of Schedule II, III, IV and V controlled substances were lost or stolen and possibly diverted."[317]

765. September 2018 minutes of an Oklahoma State Board of Pharmacy meeting reflect that an Oklahoma "Wal-Mart Pharmacy was charged with multiple violations of state and federal regulations and rules including establishing and maintaining effective controls against diversion of prescription drugs."[318] Walmart agreed to pay a fine to resolve those alleged violations.

d) Rite Aid

766. In January 2019, Rite Aid paid $177,000 into the Nalaxone Fund for the State of Massachusetts to resolve allegations that it failed to follow regulations designed to prevent substance use disorder in its dispending of controlled substances, including opioids. As part of the agreement, Rite Aid agreed to improve its dispensing practices.

767. In 2018, Rite Aid also agreed to pay a $300,000 settlement for filling Schedule III controlled substance prescriptions in excess of the maximum dosage units allowed to be

[316] Associated Press, *Wal-Mart Settles Drug Records Accusation*, (Jan. 7, 2009), http://prev.dailyherald.com/story/?id=262762.
[317] *Id.*
[318] Minutes September 26, 2018, Oklahoma State Board of Pharmacy, https://www.ok.gov/pharmacy/documents/Min%20September%202018.pdf (last visited Oct. 22, 2020).

dispensed at one time.

768. In 2017, Rite Aid paid $834,200 in civil penalties to resolve allegations by the DEA that Rite Aid pharmacies in Los Angeles dispensed controlled substances in violation of the CSA. The DEA's "investigation revealed the incorrect or invalid registration numbers were used at least 1,298 times as a result of Rite Aid's failure to adequately maintain its internal database."[319] The settlement also "resolve[d] allegations that Rite Aid pharmacies dispensed, on at least 63 occasions, prescriptions for controlled substances written by a practitioner whose DEA registration number had been revoked by the DEA for cause."[320]

769. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the CSA.

770. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

F. Defendants' targeted their illegal conduct nationwide, including in Plaintiffs' states.

771. The opioid epidemic led to increased opioid use and increased births of children exposed to opioid in-utero. Because of Defendants' misconduct, all of Plaintiffs' states saw a precipitous rise in opioid use, opioid related deaths, and NAS births between 1999 and recent

[319] DEA, *Rite Aid Pays $834,200 Settlement for Alleged Controlled Substances Act Violations in Los Angeles* (March 9, 2017), https://www.dea.gov/press-releases/2017/03/09/rite-aid-pays-834200-settlement-alleged-controlled-substances-act.
[320] *Id.*

years.[321]

772. In Kentucky, the number of annual opioid-related overdose deaths increased nearly 1000% from 1999 to 2018.[322] At relevant times, Kentucky has had the fifth highest death rate due to drug overdoses in the nation.[323] From 2006 to 2015, Kentucky had more opioid prescriptions than people.[324] The latest data shows that while rates of prescriptions are down, they are still prolific: in 2018, Kentucky providers wrote 79.5 opioid prescriptions for every 100 persons.[325] Limited data of hospitalizations show that the number of NAS hospitalizations in Kentucky rose from about 250 in 2008 to approximately 1,100 in 2018.[326] In addition to causing increased rates of NAS, rates of involvement of family services demonstrates the devastating impact of Kentucky's opioid epidemic on families. The number of children in foster care in Kentucky increased from 6,000 to 8,000 between 2012 and 2017, which one foster parent recruiter attributed directly to the opioid epidemic.[327]

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[321] Some states saw declines in opioid-related deaths in the most recent years (2017-present) because of increased awareness and government-led and voluntary measures to curb opioid prescribing. However, progress that was made in curbing opioid misuse and opioid-related deaths has been reversed since the onset of the Covid-19 pandemic. American Medical Association, Issue brief: Reports of increases in opioid-and other drug-related overdose and other concerns during COVID pandemic (October 6, 2020), https://www.ama-assn.org/system/files/2020-10/issue-brief-increases-in-opioid-related-overdose.pdf

[322] Kentucky: Opioid-Involved Deaths and Related Harms, NIH: National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/kentucky-opioid-involved-deaths-related-harms (last visited Oct. 22, 2020).

[323] 2018 Kentucky Health Issues Poll, Foundation for a Healthy Kentucky, https://www.healthy-ky.org/res/images/resources/KHIP-substance-use-FINAL.pdf (last visited Oct. 22, 2020).

[324] Dan Clark, *Do Some States Have More Opioid Prescriptions than Residents?*, Politifact New York (Sept. 19, 2017); *see also* CDC prescribing data listing 122.6 as the prescription rate for KY in 2006, 130.8 in 2007, 136.6 in 2008, 135.2 in 2009, 136.5 in 2010, 137 in 2011, 127.9 in 2012, 111.7 in 2013, 110 in 2014, and 102.6 in 2015: https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html.

[325] *Id.*

[326] HCUP Fast Stats – Neonatal Abstinence Syndrome (NAS) Among Newborn Hospitalizations, Agency for Healthcare Research and Quality, www.hcup-us.ahrq.gov/faststats/NASServlet (last visited Oct. 22, 2020) (hereinafter, "HCUP Fast Stats").

[327] *States hit hard by opioid crisis see increase in foster care kids*, North Jefferson News, Jan. 19,

773. West Virginia has been ravaged by the opioid epidemic. Indeed, West Virginia has the highest rate of opioid-related overdose deaths in the country. In 2017, there were 833 drug overdose deaths involving opioids in West Virginia—a rate of 49.6 deaths per 100,000 persons. This is double the rate in 2010 and threefold higher than the national rate of 14.6 deaths per 100,000 persons.[328] Nationwide, fatal overdoses from prescription opioids more than doubled between 2005 and 2016. Big Pharma specifically targeted West Virginia, aggressively marketing the drugs to doctors and pharmacists while pouring over 780 million doses of prescription painkillers into the state over the course of six years.[329] The drug companies identified particular counties and towns, and even particular pharmacies, to flood with opioids. For example, Kermit, a town with a population of 392, received nearly 9 million hydrocodone pills over the course of two years.[330] One pharmacy in Oceana received nearly 600 times as many oxycodone pills as a nearby Rite Aid.[331] Between 2007 and 2013, the incidence of NAS increased from 7.74 per 1000 live births per year to 31.56 per 1000 live births per year.[332] Researchers examined a 15-month period from October 1, 2016 to December 31, 2017, and found incidence of NAS in 52.6 per 1000 live births among West Virginia residents.[333]

774. In Illinois, the number of annual opioid-related overdose deaths increased from

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2017.

[328] Debbie Cenziper, et al., The Opioid Files, Washington Post (Oct. 18, 2019), https://www.washingtonpost.com/graphics/2019/investigations/west-virginia-opioid-legal-battle-foster-care/

[329] Eric Eyre, Drug firms poured 780M painkillers into WV amid rise of overdoses, Charleston Gazette-Mail (Dec. 17, 2016), https://www.wvgazettemail.com/news/health/drug-firms-poured-m-painkillers-into-wv-amid-rise-of/article_78963590-b050-11e7-8186-f7e8c8a1b804.html

[330] *Id.*

[331] *Id.*

[332] Amna Umer, et al., Capturing the statewide incidence of neonatal abstinence syndrome in real time: the West Virginia experience, 86 Pediatric Research 5 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6435397/

[333] *Id.*

approximately 500 to approximately 2,200 from 1999-2017.[334] From 2013 to 2016, the number of prescription opioid overdose deaths in Illinois quadrupled.[335] Total opioid prescriptions in Illinois rose from about 7 million in 2008 to a peak of almost 9 million in 2014.[336] Rates of NAS in Illinois continue to rise. From 2011 to 2017, the incidence of NAS increased by 64%, from 1.77 per 1,000 deliveries to 2.90.[337]

775. In Maine, the number of annual opioid-related overdose deaths increased by approximately 700% from 1999 to 2017.[338] Maine was one of the first areas in the nation to see high numbers of opioid prescriptions, and to see a corresponding increasing in abuse and diversion of opioids. Between 1995 and 2001, the number of patients treated in Maine for opioid abuse increased 460%.[339] Between 2006 and 2012, 400 million prescription pain pills were distributed in Maine, and in 2012, the state had the highest opioid prescribing rate in the nation, with an average of 21.8 prescriptions per 100 people.[340] In the first and second quarters of 2020, there were 127 and 132 total drug overdose deaths in the state, respectively, with 82% of those deaths caused by at least one opioid. Both quarters represent an increase in deaths

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[334] Illinois: Opioid-Involved Deaths and Related Harms, NIH: National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/illinois-opioid-involved-deaths-related-harms (last visited Oct. 22, 2020).
[335] IDPH Opioid Data Dashboard, Illinois Department of Public Health, http://www.dph.illinois.gov/opioids/idphdata?data1=abmlb5 (last visited Oct. 22, 2020).
[336] Opioid Prescriptions and Overdose Deaths in Illinois, Illinois Criminal Justice Information Authority, https://app.icjia.cloud/app_direct/opioid-prescriptions-and-overdose-deaths-in-illinois/ (last visited Oct. 22, 2020).
[337] Illinois Department of Public Health, Neonatal Abstinence Syndrome Advisory Committee: Final Report to the General Assembly, at 9 (May 31, 2019), available at http://dph.illinois.gov/sites/default/files/publications/nas-annual-report-march-2019.pdf.
[338] Maine: Opioid-Involved Deaths and Related Harms, NIH: National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/maine-opioid-involved-deaths-related-harms (last visited Oct. 22, 2020).
[339] Van Zee, *Promotion and Marketing*, *supra* n.41.
[340] Dan Neumann, *Collins took opioid-linked contributions, opposed corporate accountability* (Aug. 13, 2019), https://mainebeacon.com/collins-took-opioid-linked-contributions-opposed-corporate-accountability/.

compared with the last quarter of 2019.[341] Data from the Maine Maternal, Fetal, and Infant Mortality Review Panel show that in 2018, Maine's NAS rate was higher than the national average, with 34.7 cases for every 1,000 births (compared to a national 2015 rate of just 6.4). Also in 2018, 7% of babies born in Maine had been exposed to substances in utero.[342]

776. In Maryland, the number of annual opioid-related overdose deaths increased by approximately 400% between 1999 and 2018.[343] Opioid-related deaths in Maryland quadrupled between 2010 and 2018 and, after a decrease in 2019, increased in the first quarter of 2020, with preliminary data showing a 2.6% increase over the same time period in 2019.[344] Between 2007 and 2012, more than 40% of all alcohol and drug overdose deaths in Maryland involved at least one prescription opioid.[345] Admissions to substance use disorder treatment programs also show the impact of prescription pain pills flooding Maryland: between 2008 and 2012, there was a 110% increase in admission to state-supported treatment programs, with prescription opioid-related admissions increasing by 116%.[346] Rates of NAS births have increased in Maryland over the last decade. Limited data of hospitalizations show that the number of NAS

[341] Eesha Pendharkar, *Maine drug deaths rose as the state shut down due to the COVID-19 pandemic* (July 17, 2020), https://bangordailynews.com/2020/07/17/news/maine-drug-deaths-rose-as-the-state-shut-down-due-to-the-covid-19-pandemic/.
[342] Eesha Pendharkar, *The troubling effects of the opioid crisis on Maine children* (Oct. 10, 2019), https://bangordailynews.com/2019/10/10/news/bangor/what-we-know-and-dont-know-about-how-maines-opioid-crisis-has-affected-kids/.
[343] Maryland: Opioid-Involved Deaths and Related Harms, NIH: National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/maryland-opioid-involved-deaths-related-harms (last visited Oct. 22, 2020).
[344] Meredith Cohn, *Opioid-related deaths make a disappointing uptick in early 2020, possibly related to coronavirus* (Jun. 11, 2020), https://www.baltimoresun.com/health/bs-hs-overodose-deaths-first-quarter-20200611-r5pvlyzqrffo3ndvwc2oh3y7cy-story.html.
[345] Prescription Drug Abuse, Maryland Department of Health: Behavioral Health Administration, https://bha.health.maryland.gov/pdmp/Pages/Prescription-Drug-Abuse.aspx (last visited Oct. 22, 2020).
[346] *Id*.

hospitalizations in Maryland increased from approximately 515 in 2008 to 946 in 2017.[347] In 2014, a CDC study ranked Maryland fifth on a list of states with the highest rates of opioid use by pregnant women.[348] That year, the rate of opioid-dependent mothers in the state was 11.7 cases per 1,000 deliveries.[349]

777. In Minnesota, the number of annual opioid-related overdose deaths increased by approximately 900% between 1999 and 2017.[350] At the state's peak in 2017, 422 people died from opioid-involved overdoses. Non-fatal opioid-involved overdoses have continued to increase through 2019, with hospital discharge data indicating that emergency room visits for overdoses involving an opioid increased from 1,618 in 2016 to 2,923 in 2019.[351] Between 2006 and 2012, the number of opioid pills distributed in Minnesota increased steadily from around 90 million to more than 140 million pills. The same data show that a total of 842 million pills were distributed in the state.[352] Between 2012 and 2016, there were 1,839 cases of NAS in Minnesota.[353] Over that time period, the NAS rate per 10,000 live births increased from 35.9 in 2012 to 71.4 in 2015, and remained high at 60.0 in 2016.[354]

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[347] HCUP Fast Stats, *supra* n.326.
[348] Elizabeth Janney, *Maryland Has 5th Highest Rate Of New Moms Addicted To Opioids* (Aug. 21, 2018), https://patch.com/maryland/baltimore/maryland-has-5th-highest-rate-new-moms-addicted-opioids.
[349] *Id*.
[350] Minnesota: Opioid-Involved Deaths and Related Harms, NIH: National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/minnesota-opioid-involved-deaths-related-harms (last visited Oct. 22, 2020).
[351] Opioids: Drug Overdose Dashboard, MN Department of Health, https://www.health.state.mn.us/opioiddashboard (last visited Oct. 22, 2020).
[352] Jon Collins, *Data: Nearly 1 billion pain pills flooded Minnesota during height of opioid crisis* (Aug. 5, 2019), https://www.mprnews.org/story/2019/08/05/data-nearly-1-billion-pain-pills-flooded-minnesota-during-height-of-opioid-crisis.
[353] Minnesota Department of Health, Neonatal Abstinence Syndrome (Aug. 8, 2019), available at https://www.health.state.mn.us/communities/opioids/documents/NASmndatabrief.pdf.
[354] *Id*.

778. In New Hampshire, the number of annual opioid-related overdose deaths increased by approximately 900% from 1999 to 2016.[355] New Hampshire is one of five states with the highest rates of opioid deaths: in 2017 there were 424 opioid overdose deaths, or an age-adjusted rate of 34 deaths per 100,000 persons. This was more than two times the national average.[356] Between 2006 and 2012, New Hampshire received 280 million oxycodone and hydrocodone pills, or about 36 pills per person, per year.[357] NAS births in New Hampshire increased fivefold from 2005 to 2015, with NAS births accounting for 2.4% of live hospital births that year.[358] According to a United Hospital Fund report, New Hampshire has the second highest rate of children affected by the opioid epidemic nationwide, with a rate of 51 per 1,000 children affected.[359] Due to the severity of its crisis, New Hampshire was also one of ten states selected in 2019 to receive a five-year medical grant designed to improve treatment for pregnant mothers suffering from opioid misuse disorder.[360]

779. In New York, the number of annual opioid-related overdose deaths increased

[355] New Hampshire: Opioid-Involved Deaths and Related Harms, NIH: National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/new-hampshire-opioid-involved-deaths-related-harms (last visited Oct. 22, 2020).
[356] New Hampshire Opioid Summary, National Institute on Drug Abuse (2019), available at https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/21974-new-hampshire-opioid-summary_0.pdf.
[357] Jordyn Haime, *DEA: N.H. Received 280 Million Opioid Pills Over Six Years* (July 24, 2019), https://www.nhpr.org/post/dea-nh-received-280-million-opioid-pills-over-six-years#stream/0.
[358] Kristin Smith, As Opioid Use Climbs, Neonatal Abstinence Syndrome Rises in New Hampshire, University of New Hampshire: Carsey Research (2017), available at https://scholars.unh.edu/cgi/viewcontent.cgi?article=1330&context=carsey.
[359] United Hospital Fund, The Ripple Effect: National and State Estimates of the U.S. Opioid Epidemic's Impact on Children, at 8 (Nov. 2019), available at https://uhfnyc.org/media/filer_public/6e/80/6e80760f-d579-46a3-998d-1aa816ab06f6/uhf_ripple_effect_national_and_state_estimates_chartbook.pdf.
[360] Jason Moon, *N.H. to Receive Medicaid Grant for Pregnant Mothers Struggling With Opioids* (Dec. 19, 2019), https://www.nhpr.org/post/nh-receive-medicaid-grant-pregnant-mothers-struggling-opioids#stream/0.

from approximately 500 to 3,000 from 1999 to 2017.[361] In 2015, prescription opioids factored into about half of all drug-related deaths, and in two-thirds of opioid-related deaths.[362] That year, nearly 9 million opioid prescriptions were dispensed in the state.[363] Between 2016 and 2017, there was a 7% increase in opioid-related overdose deaths and an 11% increase in emergency room visits due to opioid overdoses in New York.[364] The state has also seen a significant increase in clients reporting opioids as a substance of abuse, as measured when they were admitted to state Substance Abuse Services: from 2010 to 2018, the rate increased from 330.7 to 368.9 per 100,000 people.[365] In 2020, a poll found that 59% of New Yorkers surveyed reported that they or someone they knew had abused opioids, up from 54% two years prior.[366] The New York State Department of Health reports that the rate of opioid overdose deaths for females of reproductive age (18 to 44 years old) triple from 2010 to 2016.[367] Maternal opioid use correlated with an increase in the incidence of NAS in newborns: the agency also reported that between 2010 and 2014, the rate of NAS in New York increased 79%, to 5.2 cases per 1,000 live births in 2014.[368]

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[361] New York: Opioid-Involved Deaths and Related Harms, NIH: National Institute on Drug Abuse, https://www.drugabuse.gov/drug-topics/opioids/opioid-summaries-by-state/new-york-opioid-involved-deaths-related-harms (last visited Oct. 22, 2020).
[362] Targeting an Epidemic: Opioid Prescribing Patterns by County in New York State, NYS Health Foundation (December 2017), available at https://nyshealthfoundation.org/wp-content/uploads/2017/12/targeting-opioid-epidemic-new-york-state-dec-2017.pdf.
[363] *Id*.
[364] New York State Opioid Annual Report 2019, New York State Department of Health, https://www.health.ny.gov/statistics/opioid/data/pdf/nys_opioid_annual_report_2019.pdf.
[365] *Id*.
[366] Bethany Bump, *More New Yorkers know someone who abuses opioids or died in an overdose, Siena survey finds* (July 19, 2020), https://www.timesunion.com/news/article/Siena-poll-More-in-NY-touched-by-opioids-as-15413678.php.
[367] New York State Opioid Use in Pregnancy & Neonatal Abstinence Syndrome Project, New York State Perinatal Quality Collaborative, https://www.albany.edu/cphce/nyspqcpublic/02_opiod_use_disorder_project_about.shtml (last visited Oct. 22, 2020).
[368] *Id*.

G. Plaintiff School Districts Have Been Damaged As A Result Of Defendants' Illegal Conduct.

780. Public schools have not been spared of the ravages of the opioid epidemic: staff, parents, and students have fallen victim to opioid addiction. And children born to opioid-addicted parents are innocent victims of the epidemic, with their lives permanently impaired by addiction from time *in utero*. Approximately 75 to 90 percent of children exposed to opioid use in the womb are born with Neonatal Abstinence Syndrome (NAS).[369] NAS is essentially the process of the newborn infant going through withdrawal from the *in utero* drug addiction, and it is a condition that is accompanied by serious and often chronic developmental disabilities. A disproportionate number of these children require enhanced educational services, including, but not limited to special education programs.

781. Opioid-exposed and NAS children have 2.7 times the odds of having a severe intellectual disability;[370] 2.43 times the odds of having autism spectrum disorder;[371] are 2.5 times more likely to fail to meet educational standards in third through seventh grade;[372] and they are more than 10 times more likely to be diagnosed with ADHD.[373]

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[369] Denise J. Maguire, et al., Long-Term Outcomes of Infants with Neonatal Abstinence Syndrome, 35 Neonatal Network 5 (2016).

[370] Su Lynn Yeoh; John Eastwood, FRACP, PhD; Ian M. Wright, MBBS, FRACP; Rachael Morton, MScMed, PhD; Edward Melhuish, PhD; Meredith Ward, MBBS, FRACP, PhD; Ju Lee Oei, MBBS, FRACP, MD, *Cognitive and Motor Outcomes of Children With Prenatal Opioid Exposure: A Systematic Review and Meta-analysis*, 2 JAMA Network Open 7 (2019), doi:10.1001/jamanetworkopen.2019.7025.

[371] Rubenstein, E., Young, J. C., Croen, L. A., DiGuiseppi, C., Dowling, N. F., Lee, L-C., ... Daniels, J., *Brief Report: Maternal Opioid Prescription from Preconception Through Pregnancy and the Odds of Autism Spectrum Disorder and Autism Features in Children*, 49 Journal of Autism and Developmental Disorders (2018), https://doi.org/10.1007/s10803-018-3721-8.

[372] Oei JL, Melhuish E, Uebel H, et al. *Neonatal abstinence syndrome and high school performance*, 139 Pediatrics 2 (2017).

[373] Eivind Sirnes, Leif Oltedal b,c, Hauke Bartsch d, Geir Egil Eide, Irene B. Elgen, Stein Magnus Aukland. Brain morphology in school-aged children with prenatal opioid exposure: A structural MRI study, Early Human Development 106–107 (2017). In addition, eighty percent of children with ADHD receive school-based services via federally mandated Individual Education

782. In a Tennessee study, children with a history of NAS were found to be significantly more likely to develop an educational disability and be eligible for special education services when compared with children who had no history of NAS. The study found that a significantly higher proportion of children with a history of NAS were diagnosed with educational disabilities of developmental delay and speech and language impairment, and a significantly higher number of students with NAS received therapies or services than those without a history of NAS.[374]

783. Plaintiff school districts are required by state and federal law to make considerable expenditures to accommodate and educate students with special learning needs, and they are required to proactively identify students with disabilities and provide them with appropriate services.

784. Federal law also requires Plaintiff school districts to expend resources to actively seek out and identify all children from birth through age 21 in their district who may be eligible for special education and related services and to evaluate such children.[375]

785. Each of Plaintiffs' states have been hit hard by the opioid epidemic, and as a result, each state has seen an increase in NAS births.

786. Plaintiff school districts have shouldered the increased cost of educating students who were exposed to prescription opioids *in utero* during the opioid epidemic that Defendants

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Plans (IEP) or services pursuant to Section 504 of the Rehabilitation Act. Melissa L. Danielson, MSPH, Susanna N. Visser, DrPH, Andrea Chronis-Tuscano, PhD, and George J. DuPaul, PhD. A National Description of Treatment among United States Children and Adolescents with Attention-Deficit/Hyperactivity Disorder. 192 J Pediatr. 240–46.e1. (2018), doi: 10.1016/j.jpeds.2017.08.040.

[374] Mary-Margaret A. Fill, et al., Educational Disabilities Among Children Born with Neonatal Abstinence Syndrome, 142 Pediatrics 3 (2018), https://pediatrics.aappublications.org/content/142/3/e20180562.

[375] 34 C.F.R. § 300.111.

purposely caused. It will continue to bear the financial burden of educating these students for the foreseeable future, as subsequent birth cohorts reach school age.

787. Plaintiff school districts also provide medical insurance coverage, workers' compensation, and long-term disability insurance to their employees. Plaintiffs that are self-insured have paid for claims for prescription opioids and treatment for addiction to prescription opioids for its employees through insurance and workers compensation. Upon information and belief, many of these prescription opioids were inappropriately prescribed to treat chronic pain.

V. CLASS ALLEGATIONS.

788. Plaintiffs bring this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of

a. Nationwide Class:

All public school districts nationwide.[376]

b. Illinois Subclass

All public school districts in the State of Illinois.

c. West Virginia Subclass

All public school districts in the State of West Virginia.

d. Kentucky Subclass

All public school districts in the State of Kentucky.

e. Maine Subclass

All public school districts in the State of Maine.

f. New Hampshire Subclass

[376] Unless otherwise specified, references to "the Class" in this complaint refer to both the State and Nationwide Classes.

All public school districts in the State of New Hampshire.

g. Minnesota Subclass

All public school districts in the State of Minnesota.

h. Maryland Subclass

All public school districts in the State of Maryland.

i. New York Subclass

All public school districts in the State of New York.

789. Plaintiffs are members of the Classes they seek to represent.

790. The proposed class definitions are intended to be subject to revision if facts adduced in discovery suggest desirable or necessary refinements to it, including but not limited to the addition of subclasses, if appropriate.

791. The members of each of the Classes are sufficiently numerous that joinder of all members is impracticable. On information and belief there are 12,884 members of the Nationwide Class.

792. Questions of fact and law common to the Classes are both well-suited to class-wide adjudication and predominate over any questions affecting only individual class members. These common, predominating questions include, but are not limited to: a) Whether the Defendants conspired to violate RICO in the marketing and dissemination of prescription opioids; b) Whether Defendants were, or reasonably should have been, aware that prescription opioids were highly addictive, not proper for long-term treatment, were being over-prescribed, and were causing an addiction epidemic leading to addiction, joblessness, homelessness, and death among users; c) Whether Defendants were, or reasonably should have been, aware that use of prescription opioids in pregnant women leads to Neonatal Abstinence Syndrome (NAS), and

children born with NAS exhibit higher rates of behavioral and emotional disorders and cognitive disabilities, necessitating special education services; d) Whether children born to opioid-addicted parents disproportionately require and qualify for enhanced educational services, including special education services; e) Whether Defendants misrepresented that prescription opioids were not highly addictive and were in fact proper for long term use; f) Whether Defendants took reasonable steps to warn doctors, pharmacists, pregnant women, and the public of the highly addictive qualities of prescription opioids and the potentially catastrophic results of opioid use during pregnancy; g) Whether Defendants were negligent.

793. Plaintiffs' claims are typical of the claims of other class members in that they have experienced a measurable increase in rates of 1) opioid-related learning disabilities among children of opioid-addicted parents for whom it is required to provide enhanced education and services, including under the Americans with Disabilities in Education Act, Section 504 of the Rehabilitation Act of 1973, and Family Education and Privacy Rights Act to provide special education resources; 2) addiction among employees for whom it provides healthcare; 3) addiction among students, for whom it provides counseling, special education, and crisis intervention.

794. Plaintiff will fairly and adequately represent and protect the interests of the class. It has retained experienced and accomplished counsel who are able and prepared to expend the resources necessary to litigate this case. A class action is superior to other methods for fairly and efficiently adjudicating this controversy. Alternatively, class-wide liability under the theories advanced in this complaint could properly be certified under Rule 23(c)(4).

VI. LEGAL CAUSES OF ACTION.

COUNT I: VIOLATION OF RACKETEER INFLUENCED CORRUPT ORGANIZATIONS ACT (18 U.S.C. § 1962-(c)–(d)) (Against all Defendants)

795. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

796. Count I is brought by Plaintiffs on behalf of themselves and the Nationwide Class and state subclasses.

797. At all relevant times, Defendants have been "person[s]" under 18 U.S.C. §1961(3) because they are capable of holding, and do hold, a "legal or beneficial interest in property."

798. RICO makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

799. RICO makes it unlawful for "any person to conspire to violate" the provisions of 18 U.S.C. §1962(c). 18 U.S.C. §1962(d).

800. As alleged herein, at all relevant times, Defendants moved aggressively to capture a large portion of the opioid sales market. In so doing, the Manufacturing Defendants launched an aggressive nationwide campaign over-emphasizing the under-treatment of pain and deceptively marketing opioids as being: (a) rarely, if ever, addictive; (b) safe and effective for the treatment of chronic long-term pain and everyday use; (c) abuse resistant or deterrent; and/or (d) safe and effective for other types of pain for which the drugs were not approved. All Defendants knowingly failed to report suspicious orders as required by state and federal law, thereby inundating the market with opioids.

801. In particular, Defendants, along with other entities and individuals, were employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (the "Opioid Fraud Enterprise"), whose purpose was to deceive opioid prescribers, the public and regulators into believing that: (a) opioids were safe and effective for the treatment of long-term chronic pain; (b) opioids presented minimal risk of addiction; and/or (c) Defendants were in compliance with their state and federal reporting obligations. In participating in these enterprises, Defendants sought to maximize revenues from the design, manufacture, sale and distribution of opioids which, in fact, were highly addictive and often ineffective and dangerous when used for chronic long-term and other types of pain.

802. As a direct and proximate result of their fraudulent scheme and common course of conduct, Defendants were able to extract billions of dollars of profit. As explained in detail below, Defendants' years-long misconduct violated 18 U.S.C. §1962(c)-(d).

A. The Opioid Fraud Enterprise.

803. At all relevant times, Defendants, along with other individuals and entities, including unknown third parties involved in the marketing and sale of opioids, operated an "enterprise" within the meaning of 18 U.S.C. §1961(4), because they are a group of individuals associated in fact, even though they are not a collective legal entity. The Opioid Fraud Enterprise: (a) existed separately from each of its component entities; (b) existed separately from the pattern of racketeering in which Defendants engaged; and (c) constituted an ongoing organization consisting of legal entities, including, but not limited to, the Manufacturing Defendants, the Distributor Defendants, Caremark, pharmacies, employees and agents of the FSMB, APF, AAPM, APS, and APA, as well as other entities and individuals, including physicians.

804. Within the Opioid Fraud Enterprise, there was a common communication network by which members exchanged information on a regular basis through the use of wires and mail. The Opioid Fraud Enterprise used this common communication network for the purpose of deceptively marketing, selling and distributing opioids to the general public. When their products, sales, distributions, and failure to report suspicious sales were contested by other parties, the Opioid Fraud Enterprise members took action to hide the scheme to continue its existence.

805. The participants in the Opioid Fraud Enterprise were systematically linked to each other through corporate ties, contractual relationships, financial ties and the continuing coordination of activities. Through the Opioid Fraud Enterprise, Defendants functioned as a continuing unit with the purpose of furthering the illegal scheme and their common purposes of increasing revenues and market share and minimizing their losses. Each member of the Opioid Fraud Enterprise reaped the bounty generated by the enterprise by sharing the benefit derived from increased sales of opioids and other revenue generated by the scheme to defraud prescribers and consumers and by failing to report suspicious sales.

806. The Opioid Fraud Enterprise engaged in and continues to engage in deceptive marketing of opioids as non-addictive, and as safe and effective for chronic long-term pain and for uses that are not FDA-approved. Further, the Opioid Fraud Enterprise continues to not report suspicious sales. The Opioid Fraud Enterprise has engaged in such activity for the purpose of maximizing the sale and profits of opioids. To fulfill this purpose, the Opioid Fraud Enterprise has advocated for, and caused the over-prescription and over-distribution of, opioids by marketing, promoting, advertising, and selling opioids throughout the country and across state boundaries and by failing to report suspicious sales. Their receipt of monies from these activities

has consequentially affected interstate and foreign commerce. The Opioid Fraud Enterprise's past and ongoing practices thus constitute a pattern of racketeering activity under 18 U.S.C. §1961(5).

807. The Opioid Fraud Enterprise functioned by marketing, selling, and distributing opioids to independent public schools, states, counties, other municipalities, doctors, healthcare organizations, pharmacies, and the consuming public, while failing to report suspicious sales. Through their illegal enterprise, Defendants as co-conspirators engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue for Defendants and the other entities and individuals associated in fact with the Opioid Fraud Enterprise's activities through the deceptive marketing and sale of opioids and the failure to report suspicious sales.

808. Defendants participated in operating and managing the Opioid Fraud Enterprise by directing its affairs as described in this complaint. While Defendants participated in, and are members of, the Opioid Fraud Enterprise, they have a separate existence from the Opioid Fraud Enterprise, including distinct legal statuses, different offices and roles, bank accounts, officers, directors, employees, individual personhood, reporting requirements, and financial statements.

809. Each member of the Opioid Fraud Enterprise furthered the ends of the Opioid Fraud Enterprise through the acts and omissions pled in this complaint.

810. Each Manufacturing Defendant relentlessly promoted opioids to prescribers, regulators and the public as having little to no risk of addiction, and as being safe and effective for the treatment of chronic, long-term pain and other common, everyday uses. The Manufacturing Defendants' success in maximizing sales was due to the tight collaboration among the Manufacturing Defendants through, and in collaboration with, the pain foundations—a formidable partnership that marketed to hundreds of thousands of prescribers across the

country. The relationship was strengthened, in part, by individuals, including physicians, that held different leadership roles at different times across the various entities participating in the Opioid Fraud Enterprise over the years.

811. On numerous occasions, the Manufacturing Defendants funded the pain foundations' marketing efforts. The Manufacturing Defendants specifically chose to partner with the pain foundations and individual physicians to publish and otherwise disseminate misleading pro-opioid material, knowing the public and prescribers would be more receptive to statements made by what they perceived to be scholarly, neutral, third-party sources.

812. Furthermore, all Defendants knowingly failed to design and operate a system to monitor suspicious orders of controlled substances and failed to notify the appropriate DEA field division offices in their areas of suspicious orders, including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

813. The members of the Opioid Fraud Enterprise worked together to further the enterprise by the following manner and means:

(a) jointly planning to deceptively market and manufacture opioids that were purportedly non-addictive, safe, and effective for the treatment of chronic long-term pain;

(b) concealing the addictive qualities and risks of opioids from prescribers and the public;

(c) misleading the public about the addictive nature, safety and efficacy of opioids;

(d) otherwise misrepresenting or concealing the highly dangerous nature of opioids from prescribers and the public;

(e) illegally marketing, selling and/or distributing opioids;

(f) collecting revenues and profits from the sale of such products for uses for which they are unapproved, unsafe, or ineffective; and/or

(g) failing to report suspicious sales as required by the CSA.

814. To achieve their common goals, Defendants hid from the general public the full extent of the unsafe and ineffective nature of opioids for chronic and other types of pain as described herein. Defendants suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities about the addictive, unsafe, and often ineffective nature of opioids.

815. The foregoing allegations support that Defendants were part of an association of entities that shared a common purpose, had relationships across various members of the Opioid Fraud Enterprise, and collaborated to further the goals of the Opioid Fraud Enterprise for a continuous period of time. The Manufacturing Defendants knowingly and intentionally engaged in deceptive marketing practices and incentivized pain foundations, marketing firms and physicians to do so as well. Defendants knowingly and intentionally failed to report suspicious orders as required by state and federal law and Defendants inundated the market with opioids.

B. Mail and Wire Fraud.

816. To attempt to carry out and to carry out the scheme to defraud, Defendants, each of whom is a person associated in fact with the Opioid Fraud Enterprise, did knowingly conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Fraud Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c). And Defendants employed the use of the mail and wire facilities, in violation of 18 U.S.C. §§1341 (mail fraud) and 1343 (wire fraud).

817. Specifically, Defendants have committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.*, violations of 18 U.S.C. §§1341 and 1343) within the past four years. The multiple acts of racketeering activity which Defendants committed or aided and abetted in the commission of were related to each

other and also posed a threat of continued racketeering activity. They therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Fraud Enterprise. Defendants participated in the scheme to defraud by using the mail, telephone and Internet to transmit mailings and wires in interstate or foreign commerce.

818. Defendants devised and knowingly carried out a material scheme and/or artifice to defraud regulators, prescribers, and the public to obtain money from Plaintiffs and the Class by means of materially false or fraudulent pretenses, representations, promises or omissions of material facts. For the purpose of executing the illegal scheme, Defendants committed these racketeering acts intentionally and knowingly with the specific intent to advance the illegal scheme.

819. Defendants' predicate acts of racketeering, 18 U.S.C. §1961(1), include:

(a) Mail Fraud: Defendants violated 18 U.S.C. §1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, sell and distribute the opioids by means of false pretenses, misrepresentations, promises and omissions; and

(b) Wire Fraud: Defendants violated 18 U.S.C. §1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on misrepresentations and false pretenses, promises and omissions.

820. Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery, and shipment of deceptive marketing materials, the filling of suspicious orders, and the misleading of regulators and the public as to Defendants' compliance with state and federal reporting obligations. These materials would not have been delivered, orders would not have been filled and regulators would have not been misled but for Defendants' illegal scheme, including:

(a) the FSMB's publication of opioid prescribing guidelines titled, "Responsible Opioid Prescribing: A Physician's Guide," by Fishman;

(b) the FSMB's publication of "Responsible Opioid Prescribing: A Clinician's Guide (Second Edition, Revised and Expanded)," by Fishman;

(c) the APF's publication of Exit Wounds;

(d) the AAPM's "consensus statement" and educational programs featuring Fine;

(e) the APA's publication and dissemination of "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse";

(f) false or misleading communications to the public and to regulators;

(g) failing to report suspicious orders as required by state and federal law;

(h) sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

(i) documents intended to facilitate the manufacture and sale of opioids, including bills of lading, invoices, shipping records, reports and correspondence;

(j) documents to process and receive payment for opioids, including invoices and receipts;

(k) payments to the foundations and physicians that deceptively marketed the Manufacturing Defendants' opioids;

(l) deposits of proceeds; and

(m) other documents and things, including electronic communications.

821. Defendants also used the Internet and other electronic facilities to carry out the scheme and conceal the ongoing fraudulent activities. For example, the Manufacturing Defendants made misrepresentations about opioids on their websites, YouTube, and through online ads, all of which were intended to mislead prescribers and the public about the safety, efficacy and non-addictiveness of opioids.

822. Defendants also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail with various affiliates, regional offices, divisions, distributors,

regulators, and other third-party entities in furtherance of the scheme. The mail and wire transmissions described in this complaint were made in furtherance of Defendants' scheme and common course of conduct to deceive prescribers, consumers, and regulators, oversupply the market, and fail to report suspicious sales.

823. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been concealed from Plaintiff, and they cannot be alleged without access to Defendants' books and records. However, Plaintiff has described the types of predicate acts of mail and/or wire fraud that occurred. The secretive nature of the Opioid Fraud Enterprise's activities made the unlawful tactics discussed in this complaint even more deceptive and harmful.

824. The foregoing allegations support that: (a) the Manufacturing Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceptively market their products through the use of both print and electronic outlets; and (b) all Defendants engaged in a pattern of racketeering activity by repeatedly engaging in wire and mail fraud to deceive regulators and oversupply the market while failing to report suspicious sales.

C. Conspiracy Allegations.

825. Defendants have not undertaken the practices described herein merely in parallel, but, rather, as part of a common scheme and conspiracy. In violation of 18 U.S.C. §1962(d) Defendants conspired to violate 18 U.S.C. §1962(c), as described in this complaint.

826. Defendants conspired to incentivize and encourage various other persons, firms and corporations, including third-party entities and individuals not named as Defendants in this complaint, to carry out offenses and other acts in furtherance of the conspiracy. Defendants conspired to increase or maintain revenues, increase market share, and/or minimize losses for

Defendants and their other collaborators throughout the illegal scheme and common course of conduct. In order to achieve this goal, Defendants engaged in the aforementioned predicate acts on numerous occasions. Defendants, with knowledge and intent, agreed to the overall objectives of the conspiracy and participated in the common course of conduct to commit acts of fraud and indecency in defectively marketing and/or selling opioids through the use of mail and wire fraud.

827. Indeed, for the conspiracy to succeed, each defendant had to agree to deceptively market, sell, and/or distribute opioids while failing to report suspicious sales. The unanimity of the Manufacturing Defendants' marketing tactics and all Defendants' failure to report suspicious sales gave credence to their misleading statements and omissions to prescribers, consumers, and regulators, and directly caused opioids to inundate the market nationwide.

828. Defendants knew and intended that government regulators, prescribers, consumers, and governmental entities would rely on the collective material misrepresentations and omissions made by them and the other Opioid Fraud Enterprise members about opioids and suspicious sales. Defendants knew and recklessly disregarded the cost that would be suffered by the public.

829. The Manufacturing Defendants knew that by partnering with the pain foundations and individual physicians who carried a more neutral public image, they would be able to attribute more scientific credibility to their products, thereby increasing their sales and profits.

830. Defendants also knew that by filling, and failing to report, suspicious sales, they would significantly increase their sales and profits.

831. The foregoing illustrates Defendants' liability under 18 U.S.C. §1962(d), by engaging in their pattern of racketeering and conspiring to achieve their common goal of maximizing opioid sales.

832. As described herein, Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from consumers, based on Defendants' misrepresentations and omissions. The predicate acts also had the same or similar results, participants, victims and methods of commission. The predicate acts were related and not isolated events. The predicate acts all had the purpose of generating significant revenue and profits for Defendants. The predicate acts were committed or caused to be committed by Defendants through their participation in the Opioid Fraud Enterprise and in furtherance of their fraudulent scheme.

833. As alleged in this complaint, scores of insurers, prescribers, and consumers, including Plaintiffs, relied on Defendants' representations and omissions.

834. Plaintiffs' and the Class's injuries were directly proximately caused by Defendants' racketeering activity. But for Defendants' misstatements and omissions—and the scheme employed by the Opioid Fraud Enterprise—Plaintiff and the Class would not have been forced to bear the costs of the current opioid epidemic.

835. As a direct and proximate result of each defendant's conduct and its pattern of racketeering activity, Plaintiffs and the Classes have been injured.

836. Defendants' violations of 18 U.S.C. §1962(c)-(d) have directly and proximately caused injuries and damages to Plaintiffs and the Class, and Plaintiffs and the Class are entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs and reasonable attorneys' fees in accordance with 18 U.S.C. §1964(c).

COUNT II: PUBLIC NUISANCE (Against all Defendants)

837. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

838. Count II is brought by Plaintiffs on behalf of themselves and the Nationwide Class and State Subclasses.

839. Defendants' unlawful actions have created a public nuisance under the laws of all fifty states.

840. Plaintiffs allege that Defendants' wrongful and illegal actions have created a public nuisance. Each Defendant is liable for public nuisance.

841. Defendants intentionally, unlawfully, recklessly, and negligently manufacture, market, distribute, and sell prescription opioids that Defendants know, or reasonably should know, will be diverted, causing widespread distribution of prescription opioids in and/or to the employees, parents, and students of the Plaintiff School Districts and the members of the Class, resulting in addiction and abuse, an elevated level of children born after damaging exposure to opioids before birth, crime, death, and injuries to residents nationwide, a higher level of fear, discomfort, and inconvenience to the residents and employees of Plaintiffs' and the Class' school districts, and direct costs to Plaintiffs and the Class.

842. Defendants have unlawfully and/or intentionally distributed opioids or caused opioids to be distributed without maintaining effective controls against diversion. Such conduct is illegal. Defendants' failures to maintain effective controls against diversion include Defendants' failure to effectively monitor for suspicious orders, report suspicious orders, and/or stop shipment of suspicious orders.

843. Defendants' conduct in unlawfully distributing and selling prescription opioids, or causing such opioids to be distributed and sold, when Defendants knew, or reasonably should have known, such opioids will be diverted, possessed, and/or used unlawfully nationwide, including in and around Plaintiffs' school districts, damaged Plaintiffs and the Class.

844. Defendants' actions have been of a continuing nature and have produced a significant effect upon the public's rights, including the public's right to health and safety.

845. Defendants' distribution of opioids while failing to maintain effective controls against diversion was prohibited by federal law.

846. Defendants' ongoing conduct produces an ongoing nuisance, as the prescription opioids that they allow and/or cause to be unlawfully distributed and possessed nationwide, including in Plaintiffs' school districts and those of the Class members, will be diverted, leading to abuse, addiction, crime, public health costs, and lasting damage to the mental and emotional health of children born of opioid-addicted parents.

847. Because of the continued use and addiction caused by these unlawfully distributed opioids, the public will continue to fear for its health, safety, and welfare, and will be subjected to conduct that creates a disturbance and reasonable apprehension of danger to person and property.

848. Defendants know, or reasonably should know, that their conduct will have an ongoing detrimental effect upon the public health, safety, and welfare, and the public's ability to be free from disturbance and reasonable apprehension of danger to person and property.

849. Defendants are aware, or should be aware, of the unreasonable interference that their conduct has caused for the Plaintiffs and the Class and are in the business of manufacturing, marketing, selling, and distributing prescription drugs, including opioids, which are specifically known to Defendants to be dangerous under federal law.

850. Defendants' conduct in marketing, distributing, and selling prescription opioids, which the Defendants know, or reasonably should know, will likely be diverted for non-legitimate, non-medically appropriate use, creates a strong likelihood that these illegal distributions of opioids will cause death and injuries to residents of Plaintiffs' and the Class's school districts

and otherwise significantly and unreasonably interfere with public health, safety, and welfare, and with the public's, Plaintiffs', and the Class's right to be free from disturbance and reasonable apprehension of danger to person and property.

851. It is reasonably foreseeable to the Defendants that their conduct will cause deaths and injuries to the students and staff of Plaintiffs and the Class, and will otherwise significantly and unreasonably interfere with public health, safety, and welfare, and with the public's, Plaintiffs', and the Class's right to be free from disturbance and reasonable apprehension of danger to person and property.

852. The prevalence and availability of diverted prescription opioids in the hands of irresponsible persons and persons with criminal purposes not only causes deaths and injuries, but also creates a palpable climate of fear among students, parents, and staff of Plaintiffs' and the Class's school districts where opioid diversion, abuse, and addiction are present, and where diverted opioids tend to be used frequently.

853. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries, and make Plaintiffs' and the Class's school districts safer places to work and receive an education.

854. Defendants' conduct is a direct and proximate cause of injuries to Plaintiffs and the Class, and costs borne by Plaintiffs and the Class for increased special education needs, and a significant and unreasonable interference with health, safety, and welfare, and with Plaintiffs' and the class's right to be free from disturbance and reasonable apprehension of danger to person and property.

855. Defendants' conduct constitutes a public nuisance and, if unabated, will continue to threaten the health, safety, and welfare of the students and staff of the Plaintiffs' and the Class's school districts, creating an atmosphere of fear and addiction that tears at their sense of well-being and security. Plaintiff and the Class have a clearly ascertainable right to abate conduct that perpetuates this nuisance.

856. Defendants created this nuisance of the abuse of opioids, which are dangerously addictive, and the ensuing associated plague of prescription opioid and heroin addiction. Defendants knew the dangers to public health and safety that diversion of opioids would create. However, Defendants intentionally and/or unlawfully failed to maintain effective controls against diversion through proper monitoring, reporting, and refusal to fill suspicious orders of opioids. Defendants intentionally and/or unlawfully distributed opioids or caused opioids to be distributed without reporting or refusing to fill suspicious orders or taking other measures to maintain effective controls against diversion. Defendants intentionally and/or unlawfully continued to ship, and failed to halt, suspicious orders of opioids, and/or caused such orders to be shipped. Defendants intentionally and/or unlawfully marketed opioids in manners they knew to be false and misleading. Such actions were inherently dangerous.

857. Defendants knew the prescription opioids have a high likelihood of being diverted. It was foreseeable to Defendants that, where Defendants distributed prescription opioids or caused such opioids to be distributed without maintaining effective controls against diversion, including monitoring, reporting, and refusing shipment of suspicious orders, the opioids would be diverted and create an opioid abuse nuisance nationwide, including in and around Plaintiff's and the Class's school districts.

858. Defendants acted with actual malice because Defendants acted with a conscious disregard for the rights and safety of other persons, and said actions have a great probability of causing substantial harm.

859. As a direct result of Defendants' conduct, Plaintiff and the Class have suffered actual injury and damages, including, but not limited to, significant expenses for special education programs for students exposed to opioids before birth, health services, health insurance, disability payments, other services, increased security, loss of tax revenue, costs related to opioid addiction treatment and overdose prevention, and costs associated with educating students born with NAS.

860. Plaintiffs and the Class further seek to abate the nuisance created by the Defendants' unreasonable, unlawful, intentional, ongoing, continuing, and persistent actions and omissions.

861. The public nuisance created by Defendants' actions is substantial and unreasonable—it has caused and continues to cause significant harm to the community, and the harm inflicted outweighs any offsetting benefit. The staggering rates of opioid and heroin use resulting from the Defendants' abdication of their gatekeeping and diversion prevention duties, and the Manufacturer Defendants' fraudulent marketing activities, have caused harm to Plaintiffs and the Class.

862. Plaintiffs seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia*: injunctive relief; restitution; disgorgement of profits; compensatory, treble, and punitive damages; all damages allowed by law to be paid by the Defendants; attorney's fees and costs; and pre- and post-judgment interest.

COUNT III: ILLINOIS CONSUMER FRAUD AND DECEPTIVE BUSINESS

PRACTICES ACT (Against All Defendants)

863. Count III is brought by Plaintiffs on behalf of themselves and the Illinois State Subclass.

864. Plaintiffs restate and reallege, and incorporates herein, the preceding paragraphs as if fully set forth herein.

865. At all relevant times, the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA") provided causes of action for:

> Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission or such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act," approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. 815 ILCS 505/2.

866. Pursuant to ICFA, Manufacturing Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the manufacturing, promotion, and sale of prescription opioids to individuals in and around Plaintiffs' and the Illinois SubClass's school districts.

867. Manufacturing Defendants intended that individuals in Plaintiffs' and the Illinois Subclass's school districts rely on their materially deceptive practices and purchase prescription opioids as a consequence of the deceptive practices, including Manufacturing Defendant's misrepresentations and omissions of material fact with respect to the harmful, addictive, and deadly qualities of prescription opioids.

868. Because of the dangerously addictive nature of these drugs, the Defendants' manufacturing, marketing, sales, and/or distribution practices unlawfully caused the opioid epidemic plaguing Plaintiffs' communities. Each Defendant has a non-delegable duty to guard

against and prevent the diversion of prescription opioids to other than legitimate medical, scientific, and industrial channels.

869. The Defendants also omitted material facts in their representations about themselves and their action, causing confusion or misunderstanding as to approval or certification of goods or services.

870. As alleged herein, Defendants wrongfully represented the benefits, safety, and effectiveness of prescription opioids.

871. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, significant sums of money from Plaintiffs and the Illinois Class.

872. Defendants' unfair practices include targeting vulnerable populations and lay audiences for campaigns of misinformation and oppressive marketing; disseminating deliberately false, unproven and misleading marketing in violation of state and federal law; promoting the use and sale of opioids over safer and more effective drugs without any medical or scientific basis; and rigging the medical and health insurance reimbursement system to maximize the availability of opioids for abuse, while stifling alternatives to prevent competition, to the grave detriment of society and Plaintiffs.

873. These unfair practices offend Illinois public policy, as articulated by the Illinois General Assembly opposed to the Illinois Controlled Substances Act to combat "the rising incidence in the abuse of drugs and other dangerous substances" that leads to "damage to the peace, health, and welfare of the citizens of Illinois," 720 ILCS 570/100, and public policies against fraud and for the protection of consumers. As the General Assembly has concluded, "drug addiction [is] among the most serious health problems facing the people of the State of Illinois." 745 ILCS 35/2. Defendants also worked to undermine public policy as articulated by

regulations contained in state and federal law that try to ensure the honest marketing and safe and appropriate use of pharmaceutical drugs.

874. These practices, especially the misinformation and promotion of abuse of opioids, are immoral, unethical, oppressive, and unscrupulous. Patients and medical providers, without access to Defendants' medical and scientific information, must rely on the statements and actions of Defendants and could not avoid the campaign of misinformation and lies perpetrated by Defendants over years. Patients and Plaintiffs were swamped by Defendants' regulatory and marketing campaign, coupled with the vast oversupplies of opioids by distributors. Defendants' actions tainted the scientific, medical, and regulatory communities to the extent that the opioid addiction and related harms could not reasonably be avoided.

875. The harms caused by Defendants' unfair and deceptive practices, including opioid abuse, addiction, overdose and death, compounded by the human cost of those afflicted with opioid addiction and the financial toll on the public schools system and healthcare and healthcare insurance provided by public schools, including Plaintiffs, are not outweighed by any benefits to consumers or competition. No one—except Defendants—benefits from a marketplace or healthcare system plagued by deception and misinformation, or from the over-prescription of opioids and related problems.

876. Defendants have made and/or disseminated deceptive statements and/or caused to be made or disseminated deceptive statements, including but not limited to the following:

- Creating, sponsoring, and assisting the distribution of patient education materials distributed to consumers nationwide that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

- Distributing materials to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Exclusively disseminating misleading statements in education materials to hospital doctors and staff nationwide, including in Illinois, while purportedly educating them on new pain standards; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers, including in Illinois, through in-person detailing.

877. Had it not been for Defendants' deceptive statements, Plaintiffs and the Illinois Subclass would not have made payments to cover its employees' off-label use of Defendants' drugs.

878. As a result, Plaintiffs and the Illinois Class have suffered an ascertainable loss, in an amount to be determined at trial.

COUNT IV: MARYLAND CONSUMER PROTECTION ACT (Against all Defendants)

879. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

880. Count IV is brought by Plaintiffs on behalf of themselves and the Maryland State Subclass.

881. The Maryland Consumer Protection Act provides that a person "may not engage in any unfair, abusive, or deceptive trade practice" in the sale of consumer goods. MD COML § 13-303.

882. The Maryland Consumer Protection Act provides that "any person may bring an action to recovery for injury or loss sustained by him as a result of practices prohibited" by the Act. MD COML § 13-408(a).

883. Defendants conduct violated the Maryland Consumer Protection Act.

884. Plaintiffs and the Maryland State Subclass were injured and sustained damages because of Defendants' misrepresentations and deceptive, fraudulent, and unconscionable acts in violation of the Maryland Consumer Protection Act.

COUNT V: NEW YORK GENERAL BUSINESS LAW § 349 (Against all Defendants)

885. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

886. Count V is brought by Plaintiffs on behalf of themselves and the New York State

Subclass.

887. At all relevant times, New York has prohibited "[d]eceptive acts or practices in the conduct of any business trade or commerce." N.Y. Gen. Bus. Law. § 349(a).

888. N.Y. Gen. Bus. Law § 349(h) provides a private right of action to recover actual damages to "any person who has been injured by reason of" violations of the Act.

889. Defendants conduct violated the New York General Business Law § 349.

890. Plaintiffs and the New York State Subclass were injured and sustained damages because of Defendants misrepresentations, and deceptive, fraudulent, and unconscionable acts in violation of New York General Business Law § 349.

COUNT VI: MINNESOTA PREVENTION OF CONSUMER FRAUD ACT (Against all Defendants)

891. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

892. Count VI is brought by Plaintiffs on behalf of themselves and the Minnesota State Subclass.

893. At all relevant times, the Minnesota Prevention of Consumer Fraud Act prohibited "[t]he act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby[.]" Minn. Stat. § 325F.69(1).

894. The Minnesota Private Attorney General Act provides that persons injured by violations of the Prevention of Consumer Fraud Act may bring a private action for damages. Minn. Stat. § 8.31 Subd. 3a.

895. Plaintiffs and the Minnesota State Subclass were injured and sustained damages

because of Defendants' misrepresentations and deceptive, fraudulent, and unconscionable acts in violation of the Minnesota Prevention of Consumer Fraud Act.

COUNT VII: NEW HAMPSHIRE CONSUMER PROTECTION ACT (Against all Defendants)

896. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

897. Count VII is brought by Plaintiffs on behalf of themselves and the New Hampshire State Subclass.

898. The New Hampshire Consumer Protection Act prohibits any person from engaging in "any unfair of deceptive act or practice in the conduct of any trade or commerce within this state." N.H. Rev. Stat. § 358-A.2.

899. Persons injured by violations of the New Hampshire Consumer Protection Act may be a private action or class action to recover for damages. N.H. Rev. Stat. §§ 358-A:10, A:10-a.

900. Defendants' conduct violated the New Hampshire Consumer Protection Act.

901. Plaintiffs and the New Hampshire State Subclass were injured and sustained damages because of Defendants' misrepresentations and deceptive, fraudulent, and unconscionable acts.

COUNT VIII: NEGLIGENCE: GENERAL DUTY OF CARE (Against All Defendants)

902. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

903. Count VIII is brought by Plaintiffs on behalf of themselves and the members of the Nationwide Class and state subclasses.

904. The Restatement (3rd) of Torts, § 7 recognizes a duty to exercise reasonable care "when the actor's conduct creates a risk of physical harm."

905. Defendants, collectively, manufactured, marketing, and disseminated highly dangerous and addictive prescription drugs, which creates a risk of physical harm.

906. Defendants, collectively, acted to expand the market for opioids to the treatment of chronic pain.

907. In doing so, Defendants failed to act with reasonable care in the manufacturing, marketing, promoting, selling, and/or distributing opioids for the treatment of chronic pain.

908. Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain. Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels. And Defendants knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed.

909. Nonetheless, Defendants persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids and making opioids readily available to consumers without regard to the likely harm they would cause.

910. Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

911. Defendants' conduct directly injured Plaintiffs. Defendants' conduct caused Plaintiffs to pay for increased costs for special education and related services for students exposed to opioids before birth, and to pay for or otherwise reimburse the cost of countless unnecessary and/or inappropriate opioid prescriptions, as well as the health care costs associated

with opioid addiction and abuse among their insureds, whom Manufacturing Defendants specifically targeted with their marketing schemes.

912. Defendants knew of or should have known of the foreseeable injuries to Plaintiffs caused by their failure to act with reasonable care. Defendants were aware that their goal of significantly expanding the marketplace for opioids depended in part on comprehensive coverage of opioids by insurers and third-party payors. Defendants also knew that their goal of increasing profits by promoting the prescription of opioids for chronic pain would lead directly to damaging exposure to opioids *in utero*, to an increase in health care costs for unnecessary and inappropriate opioid prescriptions to treat chronic pain and the health services and expenditures associated with the opioid epidemic for health care payors, such as Plaintiffs.

913. The aforementioned conduct was a direct breach of the duty Defendants owed to Plaintiffs and the Class, which was the proximate cause of Plaintiffs and the Class suffering damages.

COUNT IX: NEGLIGENCE: VIOLATION OF STATUTORY DUTIES
(Against All Defendants)

914. Count IX is brought by Plaintiffs on behalf of themselves and the Nationwide Class and state subclasses.

915. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

916. Reasonably prudent prescription opioid manufacturers and distributors would not have misrepresented the risks of prescription opioids, nor overstated their benefits, through publications, CMEs, and other forms of direct and indirect marketing. Reasonably prudent prescription opioid manufacturers and distributors would have implemented basic controls—required under federal law—to prevent opioid diversion in the supply chain.

917. Instead, Defendants systematically and fraudulently violated their statutory duties related to marketing controlled substances, and duties to maintain effective controls against the diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Defendants failed to meet the standard of care established by statute by looking the other way while massive quantities of prescription opioids flowed to Plaintiff's insureds. *See, e.g.*, the Controlled Substances Act, 21 U.S.C. § 801 et seq; 21 C.F.R. § 1301.74(b).

918. Every registrant—including each Defendant—is charged with being vigilant in deciding whether a customer, be it a pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes.[377] Specifically, drug manufacturers and distributors are required to maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels."[378]

919. As such, Defendants breached their duties to exercise due care in the business of manufacturing, marketing, and wholesale distribution of prescription opioids, including by filling unreasonably suspect orders over and over again, without imposing basic controls to monitor, identify, investigate, limit, and report suspicious orders for opioids. The very purpose of these duties was to prevent the harms that have directly followed: diversion of highly addictive drugs for illegal and/or non-approved purposes. Thus, the causal connection between Manufacturing and Distributor Defendants' conduct and the ensuing harm was entirely foreseeable.

920. Accordingly, Defendants breached their statutory and regulatorily established duties of care, designed specifically to prevent the harms from the abuse and misuse of

[377] *See* 21 U.S.C. § 823(e).
[378] *Id*. at § 823(b)(1); *see also id.* at § 823(a)(1).

controlled substances, including opioids, by engaging in negligence *per se*, to the significant harm of Plaintiff and its members.

921. The aforementioned conduct was a direct breach of the duty Defendants owed to Plaintiff and the Class, which was the proximate cause of Plaintiff and the Class suffering damages.

COUNT X: NEGLIGENCE: COMMON LAW FAILURE TO WARN
(Against Manufacturing Defendants)

922. Plaintiffs incorporate and re-allege each of the paragraphs above as though fully set forth herein.

923. Court X is brought by Plaintiffs on behalf of themselves and the Nationwide Class and state subclasses against the Manufacturing Defendants.

924. Manufacturing Defendants knew that opioids were highly addictive and inappropriate and unsafe for the treatment of chronic pain. Manufacturing Defendants had such actual and unequal knowledge of the risks and harms likely to result from the long-term prescription and knew or should have known that harm would result from such use, including to children exposed to opioids *in utero*.

925. To expand the market for opioids, however, Manufacturing Defendants engaged in a misinformation campaign to alter public perception of opioids, and deceive doctors, federal regulators, and the public about their addictive and unsafe qualities. Manufacturing Defendants perpetrated virtually uniform misrepresentations, concealments, and material omissions regarding (a) the safety and efficacy of opioids for the treatment of chronic pain and (b) their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

926. Because of barriers to prescribing opioids associated with their regulation as controlled substances, Manufacturing Defendants knew doctors would not treat patients with common chronic pain complaints with opioids, and insurers and other third-party payors would not cover such treatment, unless they were persuaded that opioids had real benefits and minimal risks.

927. Accordingly, Manufacturing Defendants spent millions of dollars on promotional activities and materials that falsely deny or minimize the risks of opioids while overstating the benefit of using them for chronic pain.

928. Manufacturing Defendants did not disclose to prescribers, patients, third-party payors, or the public that evidence in support of their promotional claims was inconclusive, non-existent, or unavailable, though providing such warnings and accurate information would not have imposed a burden. Rather, each Manufacturing Defendant disseminated misleading and unsupported messages that caused the target audience to believe those messages were corroborated by scientific evidence.

929. Manufacturing Defendants' misinformation campaign was intended to and did encourage patients to ask for, doctors to prescribe, and payors to pay for chronic opioid therapy.

930. Plaintiffs and the Class thus, both directly and indirectly, relied on the representations as to the efficacy and safety of opioid drugs for the treatment of chronic pain as promoted by Defendants. Because Defendants controlled all knowledge of the tests upon which the claims of opioid drugs' efficacy and safety were based, Plaintiffs and the Class, as well as other third-party payors and members of the medical community and public, were obligated to rely on Defendants' representations about opioids. Further, Defendants perpetuated this reliance by taking the steps itemized above to suppress the dissemination of any critical information

about the use of opioids for chronic pain and ensure that they were authorized for coverage and broadly distributed.

931. Manufacturing Defendants knew of widespread prescription opioid addiction and abuse, and diversion to illegal channels, including through their financial incentives and information sharing arrangements with other Defendants. Manufacturing Defendants also knew that the dangerous qualities of opioids bore a direct relationship to the volume of opioids being ordered, authorized, and prescribed.

932. Manufacturing Defendants further knew that widespread opioid addiction and abuse was harmful to the individuals consuming opioids, their unborn children, their friends, families, and communities, and those, like Plaintiffs, responsible for paying for federally-mandated special education related services for children exposed to opioids *in utero*, as well as for health care costs associated with opioid addiction and abuse among their insureds.

933. Nonetheless, Manufacturing Defendants unreasonably persisted in spreading misinformation and burying the truth about the safety and efficacy of opioids. In doing so, Manufacturing Defendants failed to take reasonable precautions in presenting opioids to the public.

934. By failing to adequately warn the public, including prescribing doctors, Plaintiffs, and the Class of the dangers of opioids, Manufacturing Defendants' conduct directly injured Plaintiffs and the Class. Because of Manufacturing Defendants' misinformation campaign, Plaintiffs and the Class paid for or otherwise reimbursed the cost of countless unnecessary and/or inappropriate opioid prescriptions, as well as the health care costs associated with opioid addiction and abuse among their insureds, whom Manufacturing Defendants' specifically targeted with their marketing schemes.

935. As a consequence of the Manufacturing Defendants' breach of their common law duty to warn, Plaintiffs and the Class have suffered damages and will continue to suffer damages.

VII. DAMAGES.

936. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs' and the Class's injuries, because Plaintiffs and the Class paid for costs associated with the opioid epidemic, as described above in language expressly incorporated herein by reference. Plaintiffs and the Class's injuries were directly and/or proximately caused by Defendants' racketeering activities. But for the RICO Defendants' conduct, Plaintiffs and the Class would not have incurred the increased costs of providing specialized education and services to students who were exposed to opioids in utero. But for the RICO Defendants' conduct, Plaintiffs and the Class would not have incurred costs related to the provision of healthcare, disability, and workers compensation to employees who were taking opioids for off label uses. But for the RICO Defendants' conduct, Plaintiffs and the Class would not have paid for prescription opioids for its employees that were used to treat chronic pain. There are no other Plaintiffs better suited to seek a remedy for the economic harms, suffered by public schools districts, at issue here. Plaintiffs and the Class seek all legal and equitable relief, as allowed by law, including, *inter alia*: actual damages (as described above in language expressly incorporated herein by reference); treble damages; equitable relief; forfeiture as deemed proper by the Court; attorney's fees; all costs and expenses of suit; and pre- and post-judgment interest.

937. Defendants' intentional and/or unlawful conduct, as described herein, resulted in direct and foreseeable, past and continuing, economic damages, which Plaintiffs and the Class have incurred and continue to incur, including: (a) costs associated with special education means, including, but not limited to, special programs for children with opioid-related learning

disabilities, or for children in need of psychological counseling due to opioid-related family crisis; (b) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; (c) costs associated with increased school security in all facilities of the school board district; (d) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (e) costs associated with increased healthcare and healthcare insurance; (f) costs regarding disability payments; (g) loss of tax revenue; and (h) treble damages, and for which Plaintiff seeks relief as to all claims and counts, as alleged herein. Plaintiff also seeks the means to abate the epidemic (created by Defendants' wrongful and/or unlawful conduct), including but not limited to, economic damages from the Defendants as reimbursement for the costs associated with past, present, and future efforts to address, pay for, and/or eliminate the aforementioned hazards to public health and safety.

938. Plaintiffs have incurred and seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' actions and omissions, including all counts alleged against Defendants. Plaintiffs do not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

939. Other than such damages specifically disavowed herein, Plaintiffs seek all legal and equitable relief, as allowed by law (for all counts alleged against Defendants), including, *inter alia*: injunctive relief; restitution; disgorgement of profits; compensatory, treble, and punitive damages; all damages allowed by law to be paid by the Defendants; attorney's fees and costs; and pre- and post-judgment interest.

VIII. PRAYER FOR RELIEF.

WHEREFORE, Plaintiffs pray that summons be issued notifying Defendants of this Complaint, and that after all legal delays, Defendants be required to answer same, and after all proceedings and a jury trial, there be a judgment in favor of Plaintiffs for all amounts commensurate with Plaintiffs' damages, including but not limited to:

(1) past, present, and future costs associated with increased educational services, including but not limited to special education needs, including, but not limited to, special programs for children with opioid-related learning disabilities, or for children in need of psychological counseling due to opioid-related family crisis; (2) past, present, and future costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; (3) past, present, and future costs associated with increased school security Plaintiffs' and Class Members' facilities; (4) past, present, and future costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (5) past, present, and future costs associated with increased healthcare and healthcare insurance; (6) past, present, and future costs regarding disability payments; (7) loss of tax revenue; (8) disgorgement of Defendants' unjust enrichment; (9) all costs and means to abate the epidemic created by Defendants' wrongful and/or unlawful conduct; (10) treble damages; (11) all other costs and damages specified herein; (12) attorneys' fees, costs, and expenses of suit; (13) pre- and post-judgment interest; and (14) such other relief as the Court deems appropriate.

For the RICO violations, an award of trebled damages as consistent with 18 U.S.C. § 1964(c) compensatory and actual damages, reasonable attorney's fees, pre-judgment interest, post-judgement interest, and costs against Defendants, each and every one of them jointly and severally, and any additional amount that this Court deems just and proper.

Plaintiffs further request all injunctive and equitable relief that the Court deems appropriate and may be permitted by law.

Plaintiffs further demand a jury trial on all issues so triable.

Date: December 16, 2020

Respectfully submitted,

/s/ Matthew J. Piers
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